Vitamin D Oral Replacement in Asthma

NCT03686150

Informed Consent Documents

Document	Date
Informed consent form for parents/caregivers	11/2/2020
Assent form for participants (children)	11/2/2020
Informed consent form for participants who reach the age of majority	11/2/2020

<*insert institution name*>

Informed Consent Form (Parents/Guardians)

Vitamin D Oral Replacement in Asthma (VDORA1)

- **We are asking you to allow your child to be in a research study.**
- **Your child does not have to be in the study.**
- **If you say yes, your child can quit the study at any time.**
- **Please take as much time as you need to make your choice.**
- **Your child can still get his/her medical care from <insert name of institution> even if your child is not in the study.**
- **During the study, we will tell you if we learn any new information that might affect whether you wish to allow your child to stay in the study.**

Why am I being asked to be in this research study?

- We are trying to learn how much vitamin D supplement children who have weight that is higher than what is considered as a healthy weight for their height and who also have asthma and low levels of vitamin D need to be given to increase their vitamin D levels. We want to give the children supplements so we can find out how long and how much vitamin D a child must take for his/her vitamin D to get to a certain level (40 ng/mL or higher) in their blood.
- This study will help us learn more about how quickly vitamin D levels rise and fall in the body of a child whose weight is higher than what is considered healthy for his/her height.

- What we learn in this study may also help us learn more about the possible relationship between vitamin D levels and asthma symptoms. It is possible that increasing the amount of vitamin D in children who have weight that is higher than what is considered as a healthy weight for their height and have asthma may improve their asthma symptoms. However, we do not know if vitamin D will help your child's asthma symptoms.
- This study may help us find out more about certain types of biological substances in your child's blood called inflammatory markers and how they might change when your child is given extra vitamin D.
- We are asking people like your child (children who have weight that is higher than what is considered as a healthy weight for their height and who have asthma) to help us. A total of 78 children were screened for Part 1 of the study and up to 171 children will be screened for Part 2 of the study. This form is only for Part 2 of the study. Children will be at least 6 years old but less than 18 years old when they begin the study. Children will be enrolled through many sites that are part of the IDeA States Pediatric Network.
- Vitamin D supplements are readily available over-the-counter, but vitamin D can also be prescribed by a physician. The study team will provide vitamin D for your child to take if he/she is in this study.
- Participation in this study is completely voluntary. There will be no change in your child's usual care if you decide you do not want him/her to be in this study.

What if I don't understand something?

- This form may have words you don't understand. Research staff will read it with you, if you like.
- You may ask as many questions as you like before you decide whether you want to allow your child to be in this study.
- You are free to ask questions at any time before, during, or after your child has entered into this study.

What if I say yes, I want my child to be in this study?

We first will see if your child qualifies to be in the study. We will:

- Ask you to sign this consent form. Your child cannot be in this study if you do not sign this form. No research and no research procedures will be done with your child if you do not sign this consent form.
- For children who are 7 years old or older, we will ask them to also sign a form that says they agree to be in this study.
- Ask your child's age or get his/her age from his/her medical record. Your child must be 6 years old or older but less than 18 years old.
- Find out if your doctor has determined your child has asthma. Your child must be diagnosed with asthma to be in this study and have a medical person (doctor or nurse) who is responsible for his/her asthma care.
- Get your child's height and weight. The height and weight measurements will be used to determine something called Body Mass Index. Body Mass Index is a measure of a person's weight for his/her height. This number helps us know if a child's weight is higher than what is considered as a healthy weight for their height. A chart will be used to compare your child's Body Mass Index to other children who are the same age and sex as him/her. To be in this study, your child must have a high Body Mass Index. Your child's Body Mass Index must be equal to or greater than 85% of all children who are the same age and sex as your child.
- Ask you and your child to initial a form documenting whether you/your child prefer to have this visit 1 blood sample taken from your child's arm or taken from a fingerstick.
- Get a sample of blood and send it to a lab to check the level of vitamin D in your child's blood. We will take about ¼ teaspoon of blood. For your child to be part of the study, the laboratory must report a number between 10 and 30 ng/mL.
- Get a urine sample and send it to a lab to check the amount of calcium in his/her urine. Calcium is a substance that can cause kidney stones. The amount of calcium in urine can go up in people taking vitamin D. We are doing this test to make sure it is safe to have your child in this study. If your child is dehydrated (does not have enough water in his/her body) this test can be wrong. The test may be repeated after your child has had a lot of water (or other appropriate liquid) to drink. If the urine test is not in the normal range and it happens more

than once, about ¾ teaspoon of blood may be taken from your child's arm. The blood will be used to check the amount of calcium and vitamin D in your child's blood.

- Ask you if your child can swallow pills. Your child must be able to swallow pills to be in this study.
- Ask if your family has plans to move out of the area in the next 9 months. Your child cannot be in the study if your family has plans to move within the next 9 months.
- Ask you questions about what medicines and supplements your child takes. If your child takes certain medicines, or has taken them recently, your child will not be allowed to be in this study.

  Your child cannot be in the study if your child is taking (or has recently taken):

  - Vitamin D supplements (above 1,000 IU per day). It is okay if he/she takes a daily vitamin that has a low level of vitamin D in it.

    If your child is taking an over-the-counter vitamin, study staff will show you photos of vitamins. You will be asked to pick the photo of the vitamin your child takes. If there is not a photo of that vitamin, you will be asked to bring in the bottle of vitamins at your next visit. You will also be asked how often your child takes the vitamin. We will use what you tell us to decide if your child may be in the study. If the daily dose of vitamin D your child takes is less than or equal to 1,000 international units (IU), it will be allowed for this study.

    While your child is in the study, you will be asked not to change his/her dose of over-the-counter vitamin D. If you make any changes in your child's over-the-counter vitamins, we will discuss this with you. If your child's vitamin D dose changes to more than 1,000 IU, you will be asked to have him/her take to a lower dose. If your child keeps taking higher (more than 1,000 IU) doses of over-the-counter vitamin D, your child will not be allowed to stay in the study.
  - Systemic glucocorticoids (prednisone or dexamethasone, for example) within the past 30 days.
  - Drug(s) that affect calcium metabolism (within the past 30 days)
  - Drug(s) that affect fat absorption (within the past 30 days)

- other drugs that may affect the results
- Study personnel will help you know what medications might be a problem.

- Ask if your child plans to make any major changes in his/her lifestyle within the next 9 months. Children who are planning to make major changes to their diet or their sun exposure (sunscreen use) cannot be in the study. Usual use of sunscreen or specific diets are allowed as long as no major changes are planned.
- Ask if any other child living in your household has entered for this study. Only 1 child per household may be part of this study.
- Check your child's medical records. Your child cannot be in the study if your child has any of the following problems:
  - Calcium metabolism problem(s)
  - Parathyroid problem(s)
  - Kidney (renal) problems, including kidney stones
  - Liver failure or abnormal liver function tests
  - History of Williams syndrome (a developmental disease that affects various body parts), sarcoidosis (an inflammatory disease that can affect various body parts), or granulomatous disease (another disease that can affect various body parts)
  - Active tuberculosis (TB)
  - Clinical evidence of rickets
  - Other disease the investigator thinks may affect study results
- If your child is a female who has started getting her period (meaning she is biologically old enough to have children), she will be given a pregnancy test. Only people who are NOT pregnant may be in this study. If your female child is biologically old enough to have children, she will be asked to either (a) not be sexually active with boys, or to (b) use some type of physical or chemical birth control.

If your child qualifies, we will do these things:

- Ask you to bring your child to the doctor's office* 8 more times. These 8 times are in addition to the initial visit that was used to see if your child qualifies. These will

be called visits 2, 3, 4, 5, 6, 7, 8, and 9. There will be about 4 weeks between all visits except between visits 1 and 2. There will be only 10 to 21 days between visits 1 and 2. Your child will be asked to take vitamin D daily between visits 2 and 6. Visits 7, 8, and 9 will be follow-up visits to see what happens to vitamin D levels in your child's blood after he/she stops taking supplements.Contact you periodically, but at least every other week, between visits 2 and 6 except those weeks when you are bringing your child into the doctor's office for a visit. You will choose how you want to be contacted. You may choose text message, phone call, or e-mail. When we contact you, we will ask if your child is taking his/her prescribed asthma medicines. We will ask if your child is taking the vitamin D that we gave you. We will ask about your child's asthma symptoms.

- At the qualifying visit (also called screening visit or visit 1) we will:
    - Ask the questions listed in the section above that starts with "*We first will see if your child qualifies to be in the study. We will…*"
    - Complete the procedures listed in the section that starts with "*We first will see if your child qualifies to be in the study. We* will…"
    - Give you diary cards. You will be asked to write information on the cards every day. You will be asked to write down your child's asthma symptoms each day. You will be asked to write down the asthma medicine(s) your child took each day.
    - Ask you to give us information about your child. This information will include your child's age, race, and ethnic background. We may ask how your family pays for medical care. We will also ask about your child's medical history.
- **Visit 2** (also called baseline visit):
    - This visit will be 10 to 21 days after you sign this consent form.
    - Your child will be told he/she will be in 1 of 2 groups. This is a random assignment. The chances of being assigned to Group A is like the chances of picking a red ball from a bag that contains 1 green ball and 2 red balls. The chances of being assigned to Group B is like the chances of picking the 1 green ball from a bag that contains 1 green ball and 2 red balls. There is no good group and no bad group, just 2 different groups. The amount of vitamin D

your child will take will depend on what group he/she is going to be in. By giving children different doses of vitamin D we will be better able to tell how children take up and use vitamin D in their bodies. Every child will get some amount of vitamin D. There is no placebo (sugar pill) group in this study.

- Your child's height and weight will be taken.
- Blood will be collected from your child's arm. The volume will be about 1½ teaspoons. Blood will be sent to a central lab to check your child's level of vitamin D. Some of the blood will also be used to check for blood levels of substances called inflammatory markers.
- You and/or your child will be asked questions about your child's medications, asthma symptoms, and health-care visits.
- Information you or your child wrote on the diary cards will be reviewed.
- You or your child will be given an Asthma Control Test. This test is a questionnaire. The questions ask you/your child about his/her asthma symptoms over the previous 4 weeks.
- You will be given vitamin D pills to give to your child.

  The amount of vitamin D in the pills will depend on which group your child is assigned to.

  Group A: A one-time amount of 50,000 IU of vitamin D during visit 2
  and then 8,000 IU every day after visit 2

  Group B: An initial dose of 600 IU of vitamin D during visit 2,
  and continue with 600 IU every day after visit 2.

  Your child will be asked to take Vitamin D pills between visits 2 and 6, but not before visit 2 or after visit 6.

- Parents will be given enough pills at visit 2 for each day between visit 2 and visit 3. More pills will be given at the next visit. The

number of pills you must take per day will be specified on your pill bottle. Your study coordinator or physician will also explain how many you need to take each day. The number of pills will be EITHER 1 per day OR 2 per day. The number you must take will depend on which group you are in.

- You will be given new diary cards to fill out over the next month. The study coordinator will explain how to fill out the cards.
- Your next visit will be scheduled for about 4 weeks (21 to 35 days) after visit 2.
- Your study coordinator will contact you at least every other week between visit 2 and visit 3.
- You will be asked if you want to come in 1 extra time before visit 3 for your child to provide an extra blood sample for vitamin D level check. THIS IS OPTIONAL.

- **Optional Visit**
  - If you choose to come for the optional visit, you and your child will be asked to initial a form documenting whether you/your child prefer to have this optional blood draw taken from your child's arm or taken from a fingerstick.
  - A blood sample will be taken from your child. This may be either from his/her arm or from a finger stick. The volume will be about ¼ teaspoon. The blood will be sent to a lab. The lab will measure the amount of vitamin D in your child's blood.

- **Visit 3**:
  - You will return any vitamin D that your child did not take.
  - Your child's diary cards, which were completed between visits, will be reviewed with you.
  - You and/or your child will be asked about
    - Your child's asthma symptoms

- Visits your child made to doctors, hospitals, and other healthcare places
- All medicines your child took
- Other medical events that may have happened

- Your child's height and weight will be measured.
- Your child will be asked to give a urine sample. The sample will be used for a lab test. The test will measure the amounts of 2 substances, calcium and creatinine.

  If the calcium/creatinine lab value is too high, your child will be asked to provide another urine sample. If the lab value is still too high, your child will be asked to let us take about ¾ teaspoon of blood from his/her arm. The blood will be used to test for levels of calcium and vitamin D in his/her blood.

- You and your child will be asked to initial a form documenting whether you/your child prefer to have this visit's blood sample taken from your child's arm or taken from a fingerstick.
- A blood sample will be taken from your child. This may be either from his/her arm or from a finger stick. If blood is obtained from your child's arm, the volume will be about 1½ teaspoons. If the blood is obtained from a finger stick, the volume will be about ¼ teaspoon. The blood will be sent to a lab. The lab will measure the amount of vitamin D in your child's blood. If your child has agreed to allow a nurse (or other trained medical professional) to collect blood from your child's arm, then a sample of your child's blood will also be used to check for blood levels of substances called inflammatory markers.
- You or your child will be given an Asthma Control Test. This test is a questionnaire. The questions will be about your child's asthma symptoms over the previous 4 weeks.
- You will be given your child's vitamin D pills for the next month. Your child will be asked to take the number of pills (1 or 2) specified by the study coordinator or study physician and written on your

child's pill bottle.. These are to be taken every day between this visit and you and your child's next visit.

- You will be given new diary cards to fill out over the next month. The study coordinator will explain how to fill out the cards.
- Your next visit (visit 4) will be scheduled for about 8 weeks from visit 2. This should be about 1 month from this visit (visit 3).
- If your child stops taking vitamin D, the study team will ask you to keep coming for follow up visits. This will help make sure your child is safe.
- Periodic (at least weekly) contact will be made by the study team between this visit and you/your child's next visit.

- **Visit 4**
  - Visit 4 will be the same as Visit 3, with the following exception:
    - If your child is female and has started her period (meaning she is old enough to get pregnant), her urine will be used for a pregnancy test. This test is in addition to the calcium/ creatinine test.
  - Visit 5 will be scheduled for 12 weeks after visit 2. This should be about 1 month from this visit (visit 4)
- **Visit 5**
  - Visit 5 will be the same as Visit 3.
  - Visit 6 will be scheduled for about 16 weeks after visit 2. This should be about 1 month from this visit (visit 5)
- **Visit 6**
  - You will return any vitamin D that your child did not take.
  - Your child's diary cards, which were completed between visits, will be reviewed with you.

- You and/or your child will be asked about
  - Your child's asthma symptoms
  - Visits your child made to doctors, hospitals, and other healthcare places
  - All medicines your child took
  - Other medical events that may have happened
- Your child's height and weight will be measured.
- Your child will be asked to give a urine sample. The sample will be used for a lab test. The test will measure the amounts of 2 substances, calcium and creatinine. If your child is female and has had her period (meaning she is old enough to get pregnant), the urine will also be used for a pregnancy test.
  - If the calcium/creatinine lab value is too high, your child will be asked to provide another urine sample. If the lab value is still too high, your child will be asked to let us take about ¾ teaspoon of blood from his/her arm. The blood will be used to test for levels of calcium and vitamin D.
- A blood sample (about 1½ teaspoons total) will be taken from your child. Tests will be done for
  - the amount of vitamin D in your child's blood
  - inflammatory markers
- You or your child will be given an Asthma Control Test. This test is a questionnaire. The questions will be about your child's asthma symptoms over the previous 4 weeks.
- You will be given new diary cards to fill out over the next month. The study coordinator will explain how to fill out the cards.
- Visit 7 will be scheduled for about 20 weeks after visit 2. This should be about 1 month from this visit (visit 6).
  - You will be contacted one time between Visit 6 and 7.

- Your child will NOT be taking vitamin D after Visit 6.

- **Visit 7**

  - Your child's diary cards, which were completed between visits, will be reviewed with you.

  - You will be asked questions about your child's asthma symptoms and other medical events that may have happened since you/your child's last visit.

  - You and your child will be asked to initial a form documenting whether you/your child prefer to have this visit's blood sample taken from your child's arm or taken from a fingerstick.

  - A blood sample will be taken from your child. This may be either from his/her arm or from a finger stick. If blood is obtained from your child's arm, the volume will be about 1½ teaspoons. If the blood is obtained from a finger stick, the volume will be about ¼ teaspoon. The blood will be sent to a lab. The lab will measure the amount of vitamin D in your child's blood. If your child has agreed to allow a nurse (or other trained medical professional) to collect blood from your child's arm, then a sample of your child's blood will also be used to check for blood levels of substances called inflammatory markers.

  - You will be given new diary cards to fill out over the next month. The study coordinator will explain how to fill out the cards.

  - Visit 8 will be scheduled for about 24 weeks after visit 2. This should be about 1 month from this visit (visit 7).

    - You will be contacted at least one time between this visit and you/your child's next visit.

- **Visit 8**

  - Visit 8 will be the same as visit 7.
  - Visit 9 will be scheduled for about 28 weeks after visit 2. This should be about 1 month from this visit (visit 8).

- **Visit 9**
    - Your child's diary cards, which were completed between visits, will be reviewed with you.
    - You will be asked questions about your child's asthma symptoms and other medical events that may have happened since visit 8.
    - You and your child will be asked to initial a form documenting whether you/your child prefer to have this visit's blood sample taken from your child's arm or taken from a fingerstick.
    - A blood sample will be taken from your child. This may be either from his/her arm or from a finger stick. If blood is obtained from your child's arm, the volume will be about 1½ teaspoons. If the blood is obtained from a finger stick, the volume will be about ¼ teaspoon. The blood will be sent to a lab. The lab will measure the amount of vitamin D in your child's blood. If your child has agreed to allow a nurse (or other trained medical professional) to collect blood from your child's arm, then a sample of your child's blood will also be used to check for blood levels of substances called inflammatory markers. These substances help the doctor know how well a person's body is responding to various factors. The result of the vitamin D level at this time will be given to you so you can discuss with your primary care provider if your child should restart taking vitamin D supplements after the study is done.

How long will this study take?

This part (Part 2) of the study will take about 8 months. You and your child will be asked to come to the doctor's office* 8 more times. The office visits will be about 1 month apart for visits 2, 3, 4, 5, 6, 7, 8, and 9. The last visit, Visit 9, will be about 7½ to 8 months from the time you sign this form.

The first visit will take about 2 hours. Visits 2 to 9 will take about 1 hour each. The periodic contacts will take about 15 minutes. The diary cards will take about 10 minutes every day between visits 1 and 6.

Who will see the information about me that is collected?

- The local study team will know your child's name and have access to your child's information.
- We will do our best to make sure no one outside the study knows that your child is a part of the study.
- Your child's study information will be sent to the lead study team for the IDeA States Pediatric Clinical Trials Network at the University of Arkansas for Medical Science. This information may include protected health information, such as date of birth, but will not include your child's name. You will be asked to sign a separate HIPAA authorization that will allow us to use protected health information we need to collect to do this study.
- We will take your child's name off of information and study samples that we collect from you during the study.
- When we share the results of the study, we will not include your child's name.
- There are people who make sure the study is running the right way. These people may see information from the study about your child. This information may include information that identifies your child. The people that may see this information are:
    - Members of the University of Arkansas for Medical Sciences (UAMS) Institutional Review Board (IRB)
    - Members of the IRB at the institution named on this form.
    - OHRP (United States Office of Human Research Protections)
    - Study monitors and other employees of the Data Coordinating and Operations Center (DCOC) for the IDeA States Pediatric Clinical Trial Network (ISPCTN)
    - National Institutes of Health (NIH)
    - Overall-study Principal Investigator (PI)
        - ✓ *INSERT LOCAL CONTEXT IF APPLICABLE*
        - ✓ *Any site-specific groups other than "local IRB," which is already listed, that may access the records or provide oversight, in*
- INSERT LOCAL CONTEXT IF APPLICABLE

- For example:
- "State law requires we tell the authorities if we learn
  - ✓ about possible child or adult abuse
  - ✓ that you or your child might hurt him/her-self or someone else

Where and how long will my information and samples be kept?

- We will code your child's information and study samples and limit access to the code. Only people who must have access will be allowed to see the information.
- Blood samples will not be kept. Samples will only be used to do the testing specified for this study.
  - Specifically, the local study team and *<insert other parties that may have access>* will have access to the code for your child's information.
- We LOCAL CONTEXT: will/will not put a copy of this form in your child's medical record.

INSERT LOCAL CONTEXT about access to medical records

  - We *will/will not* put other information about your child from the study in your child's medical record. *(Say what information will be put in the participant's medical record.)*

What if I say no, I do not want to allow my child to be in this study?

- Nothing bad will happen.
- Your child can still get his/her medical care at <insert name of institution / location here>.

What happens if I say yes, but change my mind later?

- You can remove your child from the study at any time.
- Nothing bad will happen to you or your child.
- Your child can still get medical care at <insert name of institution / location here>.
- If you decide to stop allowing your child to be a participant in the study, call <insert name of contact here> at < insert phone number of contact here>.

Can my child be taken out of the study even if I want my child to continue?

Yes, the study doctor (or head researcher) can take your child out of the study if:

- You/your child do not follow study instructions.
- There is a medical reason that it is not in your child's best interest to continue.
  - Examples of medical reasons for asking your child to stop taking vitamin D are: (1) calcium levels too high in the blood or (2) pregnancy.
  - If study personnel say your child needs to stop taking vitamin D, your child may be given a physical exam, if the doctor thinks it is necessary.
- The study is stopped for any reason.

If I stop allowing my child to be in the study, what will happen to any information or samples collected from me or my child in the study?

We will not be able to take your information/samples out of the study after it has started.

Will my child's information or samples from the study be used for anything else, including future research?

No. Your child's information and samples will be used only in this study.

Will it cost me anything to be in the study?

The study will not cost you anything. You and your insurer will not be charged for any study-related visits or blood tests. You or your insurance company will be responsible for your regular medical care that is not related to this study.

Will I be paid?

Yes. We will give your family $120.00 per visit. This is to pay for parking and travel ($20.00/visit) and for your and your child's time ($100.00/visit). You will receive $20.00 and your child will receive $100.00. You/your child will be paid INSERT LOCAL CONTEXT ON HOW AND WHEN PAYMENTS WILL BE MADE e.g. *cash, gift card, etc.)* at *the end of each visit/end of the study*.

If you change your mind and decide not to allow your child to be in the study, you and your child will only be paid for the parts your child completed.

<Insert local context on reimbursement with regard to collecting name, address, social security number, etc. as it affects study payments/reimbursements and taxable income. For example: "Study payments are taxable income. A Form 1099 will be sent to you and to the Internal Revenue Service if the payments are <insert amount> in a calendar year."

Will being in this study help my child in any way?

Being in the study may or may not help your child. The results of this study may be used in the future to help other asthmatic children who also have weight that is higher than what is considered as a healthy weight for their height. What we learn may help determine how much vitamin D must be given to such children to make sure they have the best vitamin D levels in their blood.

This study may help your child get to the healthiest amount of vitamin D in his/her blood. This could help with bone health or asthma systems, but we do not know if any of these things will happen.

What are the risks of being in this study?

The risks are:

- The risks for this study are no more than what happens in everyday life.
- Someone could find out that your child was in the study and learn something about your child that you did not want others to know. We will do our best to protect your child's privacy.
- Your child could have pain or bruising at the site where blood is collected from his/her arm.
- It is possible, but very unlikely, that your child could bleed too much, get an infection, or faint when blood is taken.
- Your child may feel uncomfortable about being asked to provide a urine sample.
- Your child may feel uncomfortable being weighed.
- You or your child may not want to answer certain questions. The questions may make you or your child feel uncomfortable. You or your child do not have to answer any questions you do not want to answer.
- Your child will not be taking vitamin D supplements between week 16 (visit 6) and week 28 (visit 9). This is a 3-month gap. His/her vitamin D level may decrease during this time. His/her vitamin D level will be checked again at week

28 (visit 9) and you will be told his/her level at that time. You and your child's primary care provider can then decide if vitamin D supplements should be restarted.

- Your child could get too much vitamin D and have a reaction to the medicine. This would be very unlikely. Vitamin D is very safe and it is hard to overdose on it. However, it is possible that your child could have an increase in calcium in his/her blood and urine. Kidney stones could occur as a result. Accidental poisoning with doses of vitamin D many times higher than used in this study have been associated with nausea and increased levels of calcium in the blood.

What if my child gets sick or hurt while he/she is in this study?

INSERT LOCAL CONTEXT

FOR EXAMPLE:
If your child gets hurt when he or she is here for the study, we will help you get the care your child needs. This may include first aid, emergency care and/or follow-up care.

- If you are not here and your child gets hurt or sick, and you think it is because of the study, do these things:
  - ✓ call your doctor or if an emergency, call 911
  - ✓ give your doctor or ER staff
    - the name of this study *(insert name of study)*
    - the name of the head researcher for this study *(insert researcher name)*
    - a copy of this form if you have it
  - ✓ call the head of the study *(insert researcher name and 24 hour phone #)*

Choose from these options:

- This treatment may be billed to you or your insurance company in the normal manner. Normally, no other form of payment is available.

  OR

- *Insert details of agreement negotiated with sponsor*

What are the alternatives to being in this study?

- Your child does not have to be in this study.
- The alternative is standard of care that you usually get from your doctor.

What if new information comes up about the study?

- We want you to know about anything that may change your mind about your child being in the study.
- The researcher will let you know by one of the following methods:
  - calling you
  - sending you a letter, an e-mail, and/or a text message
  - telling you at a follow up visit
- If you choose to stay in the study, you may be asked to sign a new version of the consent form.

Where can I find more information about this clinical trial?

A description of this clinical trial is be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website any time. The NCT number is NCT03686150.

What if I have questions?

- Please call the head researcher of the study *(insert researcher name and phone #),* if you
  - have any questions about this study
  - have questions about your and your child's rights
  - feel your child has been injured in any way by being in this study
- You can also call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if you
  - have questions about this study
  - have questions about your or your child's rights
  - can't reach the study team

- need to speak to someone not directly involved with this study

What should I do if I want to be in the study?

- Sign this form. We will give you a copy of this form to keep.

By signing the document, I am saying:

- I understand that joining this study is voluntary.
- I allow my child to be in the study.
- Someone talked with me about the information in this document and answered all my questions.
- I have been asked if I wish to talk directly to the study doctor.

I know that:

- I can stop allowing my child to be in any and all parts of the study at any time and nothing bad will happen to me or my child.
- I can call the office(s) that supervises this research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or my or my child's rights.
- <Insert LOCAL CONTEXT when applicable. For example: I can also call <*insert name of local IRB and phone number when applicable - or delete this bullet*>
- My decision will not change my child's medical care at <*insert name of institution / location*>.
- I do not give up any of my rights or my child's rights by signing this form.

I agree to allow my child to be part of this study:

Printed Name of Parent or Legal Guardian

Signature of Parent or Legal Guardian | Date (mm/dd/yyyy)

I agree to the optional visit between Visit 2 and Visit 3.

Printed Name of Parent or Legal Guardian

Signature of Parent or Legal Guardian | Date (mm/dd/yyyy)

Name of Child: _____

Person Obtaining Consent:

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent | Date (mm/dd/yyyy)

<insert local institution name>

CHILD ASSENT TO PARTICIPATE IN RESEARCH

Vitamin D Oral Replacement in Asthma (VDORA1)

We are asking you to take part in a research study because we want to learn about vitamin D levels in children who have asthma and who weigh more than what is considered healthy for their height. We want to find out how much vitamin D a child needs to take to get to a certain level (40 ng/mL) of vitamin D in his/her blood. There will be 2 groups of children in this study. One group will be called "Group A" and the other will be called "Group B." The groups will get different amounts of vitamin D. Neither group is better or worse than the other group. Which group you are in will be determined by chance. You do not get to choose which group you will be in. The chances of being assigned to Group A is like choosing a red ball from a bag that has 1 green ball and 2 red balls. The chances of being assigned to Group B is like choosing the 1 green ball from a bag that has 1 green ball and 2 red balls.

This study will take about 8 months to do.

If you agree to be in this study, we will ask you to do the following:

- Let a doctor examine you if the study team asks you to stop taking vitamin D before the end of the study and if the doctor thinks it is necessary.
- Let someone take your height and weight 6 times. This will be about 1 time every month
- Let someone get blood from your arm 2 times. The nurse or other medical professional will use a needle to get blood from your arm.
- Let someone get blood from EITHER your arm OR your finger 7 times. This means you will be asked to give blood a total of 9 different times. Two times will have to be from your arm. The other 7 times can be either from your arm or from you finger. You will be giving blood about 1 time every month. You will be able to choose if you want to give blood one extra time. If you give blood 1 extra time, you will be giving blood 10 times.
- Pee in a cup at least 5 times. If your lab test results are unusual, you could be asked to pee in a cup more often. You could also be asked to let someone get extra blood from you.
- Take vitamin D pills. You will swallow your first pill during the second visit. Starting the day after visit 2, you will be asked to swallow either 1 or 2 pills each day for about 4 months. A study team member will tell you if you need to take 1 pill each day or if you need to take 2 pills each day.
- Answer questions about your asthma and how you feel.

You may get a bruise on your arm where the blood sample will come from. You may feel uncomfortable having a needle put into your arm. If you choose to let the nurse or other trained medical professional take blood from your finger, you may feel a small sharp stab like being stuck with the end of a very small, very sharp needle. You may feel uncomfortable having your weight taken. You may feel uncomfortable being asked to pee in a cup. You may not like some of the questions we ask, but you will not have to answer any questions you do not want to answer.

It is possible that the vitamin D might help with your asthma. We do not know if it will help you.

You will receive $100.00 for each visit that you complete. This will pay for your time. *<Insert local context on how the child will receive payment.>*

If you are a girl and you have started having periods, some of your pee will be used to see if you are pregnant. LOCAL CONTEXT – INSERT e.g., Your parent(s) or guardian(s) will [or will not] be told the results of the pregnancy test.
Do not sign this form if you are a girl and you do not want to have a pregnancy test or LOCAL CONTEXT e.g. you do not want your parent or guardian to know the results of a pregnancy test. We will not tell your parent or guardian why you did not sign this form. We will only tell your parent(s) or guardian(s) that you do not want to be part of this study.

You may talk this over with your parent(s) or guardian(s) before you decide if you want to be in this study. We will also ask your parent(s) or guardian(s) if they think it is okay for you to be in this study. You do not have be in this study even if your parent(s) or guardian(s) say it is okay. Remember, being in this study is up to you. No one will be upset or mad if you don't want to do this. If you do say yes now, and later change your mind, you can stop taking part at any time. Nobody will be angry or upset with you.

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call [*insert local contact info: name and telephone number*].

Signing your name below means that you agree to be in this study. You and your parent(s) will get a copy of this form.

NAME OF STUDY PARTICIPANT

Printed Name of Participant

Signature of Participant | Date (mm/dd/yyyy)

SIGNATURE OF PERSON OBTAINING ASSENT

In my judgment the participant is voluntarily and knowingly agreeing to participate in this research study.

Printed Name of Person Obtaining Assent | Contact Phone Number

Signature of Person Obtaining Assent | Date (mm/dd/yyyy)

<*insert institution name*>

Informed Consent Form

Vitamin D Oral Replacement in Asthma (VDORA1)

- **We are asking you to be in a research study.**
- **You do not have to be in the study.**
- **If you say yes, you can quit the study at any time.**
- **Please take as much time as you need to make your choice.**
- **You can still get your medical care from <insert name of institution> even if you are not in the study.**
- **During the study, we will tell you if we learn any new information that might affect whether you wish to stay in the study.**

Why am I being asked to be in this research study?

- We are trying to learn how much vitamin D supplement children/teenagers who have weight that is higher than what is considered as a healthy weight for their height and who also have asthma and low levels of vitamin D need to be given to increase their vitamin D levels. We want to give the children/teenagers supplements so we can find out how long and how much vitamin D a child/teenager must take for his/her vitamin D to get to a certain level (40 ng/mL or higher) in their blood.
- This study will help us learn more about how quickly vitamin D levels rise and fall in the body of a child/teenager whose weight that is higher than what is considered as a healthy weight for his/her height and will also help us learn how much vitamin D is in the child's/teenager's body when he/she is given supplements.

- What we learn in this study may also help us learn more about the possible relationship between vitamin D levels and asthma symptoms. It is possible that increasing the amount of vitamin D in children/teenagers who have weight that is higher than what is considered as a healthy weight for their height and have asthma may improve their asthma symptoms. However, we do not know if vitamin D will help your asthma symptoms.
- This study may help us find out more about certain types of biological substances in your blood, called inflammatory markers, and how they might change when you are given extra vitamin D.
- We are asking people like you (children/teenagers who have weight that is higher than what is considered as a healthy weight for their height and who have asthma) to help us. A total of 78 children/teenagers were screened for Part 1 of the study and up to 171 children/teenagers will be screened for Part 2 of the study. This form is only for Part 2 of the study. Children/teenagers will be at least 6 years old but less than 18 years old when they begin the study. Children/teenagers will be enrolled through many sites that are part of the IDeA States Pediatric Network.
- Vitamin D supplements are readily available over-the-counter, but vitamin D can also be prescribed by a physician. The study team will provide vitamin D for you to take if you remain in this study.
- Participation in this study is completely voluntary. There will be no change in your usual care if you decide you do not want to be in this study.

What if I don't understand something?

- This form may have words you don't understand. Research staff will read it with you, if you like.
- You may ask as many questions as you like before you decide whether you want to be in this study.
- You are free to ask questions at any time before, during, or after you enter into this study.

What if I say yes, I want to be in this study?

It has already been determined that you qualified to be in the study.

Specifically, it has already been determined that you

- have been diagnosed with asthma,
- had weight that is higher than what is considered as a healthy weight for your height at the time you joined the study,
- had a low vitamin D level when you joined the study.

It has also already been determined that you were not taking any medications or supplements that would interfere with the results of this study. These medications and supplements included:

- Vitamin D supplements (above 1,000 IU per day),
- systemic glucocorticoids (prednisone or dexamethasone, for example) within 30 days of study start,
- drug(s) that affect calcium metabolism (within 30 days of study start),
- drug(s) that affect fat absorption (within 30 days of study start),
- other drugs that may affect the results of this study.

Furthermore your medical records were already checked to see if you had any of the following problems:

- Calcium metabolism;
- parathyroid; kidney (renal) (including kidney stones),
- liver failure or abnormal liver function tests,
- history of Williams syndrome (a developmental disease that affects various body parts),
- sarcoidosis (an inflammatory disease that can affect various body parts), or granulomatous disease (another disease that can affect various body parts),
- active tuberculosis (TB),
- clinical evidence of rickets,
- other disease the investigator thinks may affect study results.

It was determined that you did not have any of the problems listed above and that you qualified to be in this study.

Your parent(s)/guardian(s) signed a consent form and you signed an assent form for this study when you were a minor (child). You have had a birthday since your last visit for this study. On that birthday you reached the age at which you must sign the consent yourself. You must now make your own decisions about participating in medical research, but you can talk over your decision with anyone you want to before you make your decision.

We will now:

- Ask you to sign this consent form. You cannot be in this study if you do not sign this form. No research and no research procedures will be done with you if you do not sign this consent form. Since you have had a birthday and reached the age of majority, you need to sign this form yourself if you wish to stay in this study.
- Ask if you have plans to move out of the area before your participation is scheduled to end.
- Ask if you plan to make any major changes in your lifestyle before your participation is scheduled to end. Usual use of sunscreen or specific diets are allowed as long as no major changes are planned.
- If you are a female who has started getting her period (meaning you are biologically old enough to have children), you will be asked to take pregnancy test(s) according to the schedule. Only women who are NOT pregnant may be in this study. If you are a female who is biologically old enough to have children, you will be asked to either (a) not be sexually active with men, or to (b) use some type of physical or chemical birth control.

You will be asked to continue in this protocol. Overall, you have done or will be asked to do these things:

- Come to the doctor's office 8 times after the initial visit. These will be called visits 2, 3, 4, 5, 6, 7, 8, and 9. There will be about 4 weeks between all visits except between visits 1 and 2. There will be only 10 to 21 days between visits 1 and 2. You will be asked to take vitamin D daily between visits 2 and 6. Visits 7, 8, and 9 will be follow-up visits to see what happens to vitamin D levels in your blood after you stop taking supplements. Be contacted periodically, but at least every other week, between visits 2 and 6 except those weeks when you come to the doctor's office for a visit. You will choose how you want to be contacted. You may choose text message, phone call, or e-mail. When we contact you, we will

ask if you are taking your prescribed asthma medicines. We will ask if you are taking the vitamin D that we gave you. We will ask about your asthma symptoms.

- At the qualifying visit (also called screening visit or visit 1), we asked your parent(s)/guardian(s) to:
    - Answer questions to determine if you qualified to be in this study.
    - Complete the procedures listed in the section that described the qualification process
    - Complete diary cards that were given to your parents/guardians. They were asked to write information on the cards every day. They were asked to write down your asthma symptoms each day. They were asked to write down the asthma medicine(s) you took each day.
    - Give us information about you. This information will included your age, race, and ethnic background. Your parent(s)/guardian(s) may have been asked how your family pays for medical care. We asked about your medical history.
- **Visit 2 (also called baseline visit)**:
    - This visit will be 10 to 21 days after the original consent was signed.
    - You will be told you will be in 1 of 2 groups. This is a random assignment. The chances of being assigned to Group A is like the chances of picking 1 red ball from a bag that contains 1 green ball and 2 red balls. The chances of being assigned to Group B is like the chances of picking the 1 green ball from a bag that contains 1 green ball and 2 red balls. There is no good group and no bad group, just 2 different groups. The amount of vitamin D you will take will depend on what group you are going to be in. By giving children/teenagers different doses of vitamin D we will be better able to tell how children/teenagers take up and use vitamin D in their bodies. Every child/teenager will get some amount of vitamin D. There is no placebo (sugar pill) group in this study.
    - Your height and weight will be taken.

- Blood will be collected from your arm. The volume will be about 1½ teaspoons. Blood will be sent to a central lab to check your level of vitamin D. Some of the blood will also be used to check for blood levels of substances called inflammatory markers.

- You will be asked questions about your medications, asthma symptoms, and healthcare visits.

  If you are taking over-the-counter vitamin(s), study staff will show you photos of vitamins. You will be asked to pick the photo of the vitamin you take. If there is not a photo of that vitamin, you will be asked to bring in the bottle of vitamins at your next visit. You will also be asked how often you take the vitamins. If the daily dose of over-the-counter vitamin D you take is less than or equal to 1,000 international units (IU), you will not be asked to change your over-the-counter vitamins. If your daily over-the-counter vitamin dose has more than 1,000 IU of Vitamin D, you will be asked to change what you take. If you continue to take over-the-counter vitamins with more than 1,000 IU of Vitamin D, you will not be able to stay in the study.

- Information you wrote on the diary cards will be reviewed.

- You will be given an Asthma Control Test. This test is a questionnaire. The questions ask you about your asthma symptoms over the previous 4 weeks.

- You will be given vitamin D pills to take.

  The amount of vitamin D in the pills will depend on which group you are assigned to.

  Group A: A one-time amount of 50,000 IU of vitamin D during visit 2
  and then 8,000 IU every day after visit 2.

  Group B: Take your first 600 IU dose of vitamin D during visit 2
  and continue with 600 IU every day after visit 2.

  You will be asked to take Vitamin D pills between visits 2 and 6, but not before visit 2 or after visit 6.

- You will be given enough pills at visit 2 for each day between visit 2 and visit 3. More pills will be given to you at the next visit. The number of pills you must take per day will be specified on your pill bottle. Your study coordinator or physician will also explain how many you need to take each day. The number of pills will be EITHER 1 per day OR 2 per day. The number you must take will depend on which group you are in.

- You will be given new diary cards to fill out over the next month. The study coordinator will explain how to fill out the cards.

- Your next visit will be scheduled for about 4 weeks (21 to 35 days) after visit 2.

- Your study coordinator will contact you periodically, but at least every other week between visit 2 and visit 3.

- You will be asked if you want to come in 1 extra time before visit 3. This is for you to provide an extra blood sample for vitamin D level check. THIS IS OPTIONAL.

- **Optional Visit**

  - If you choose to come for the optional visit, you will be asked to initial a form documenting whether you prefer to have this optional blood draw taken from your arm or taken from a fingerstick.

  - A blood sample will be taken from you. This may be either from your arm or from a finger stick. The volume will be about ¼ teaspoon. The blood will be sent to a lab. The lab will measure the amount of vitamin D in your blood.

- **Visit 3**:

  - You will return any vitamin D that you did not take.

  - Your diary cards, which were completed between visits, will be reviewed with you.

  - You will be asked about

    - Your asthma symptoms

- Visits you made to doctors, hospitals, and other healthcare places
- All medicines you took, including over-the-counter multi-vitamins. (See visit 2 for more information about over-the-counter vitamins.)
- Other medical events that may have happened

- Your height and weight will be measured.
- You will be asked to give a urine sample. The sample will be used for a lab test. The test will measure the amounts of 2 substances, calcium and creatinine.

  If the calcium/creatinine lab value is too high, you will be asked to provide another urine sample. If the lab value is still too high, you will be asked to let us take about ¾ teaspoon of blood from your arm. The blood will be used to test for levels of calcium and vitamin D in your blood.

- You will be asked to initial a form documenting whether you prefer to have this visit's blood sample taken from your arm or taken from a fingerstick.
- A blood sample will be taken from you. This may be either from your arm or from a finger stick. If blood is obtained from your arm, the volume will be about 1½ teaspoons. If the blood is obtained from a finger stick, the volume will be about ¼ teaspoon. The blood will be sent to a lab. The lab will measure the amount of vitamin D in your blood. If you agreed to allow a nurse (or other trained medical professional) to collect blood from your arm, then a sample of your blood will also be used to check for blood levels of substances called inflammatory markers.
- You will be given an Asthma Control Test. This test is a questionnaire. The questions will be about your asthma symptoms over the previous 4 weeks.
- You will be given your vitamin D pills for the next month. You will be asked to take the number of pills (1 or 2) specified by the study

coordinator or study physician and written on your pill bottle. These are to be taken every day between this visit and your next visit.

- You will be given new diary cards to fill out over the next month. The study coordinator will explain how to fill out the cards.
- Your next visit (visit 4) will be scheduled for about 8 weeks from visit 2. This should be about 1 month from this visit (visit 3).
- If you stop taking vitamin D, the study team will ask you to keep coming for follow up visits. This will help make sure you are safe.
- Periodically (at least biweekly) contact will be made by the study team between this visit and your next visit.

- **Visit 4**
  - Visit 4 will be the same as Visit 3, with the following exception:
    - If you are a female and have started your periods (meaning you can get pregnant), your urine will be used for a pregnancy test. This test is in addition to the calcium/ creatinine test.
  - Visit 5 will be scheduled for about 12 weeks after visit 2. This should be about 1 month from this visit (visit 4)
- **Visit 5**
  - Visit 5 will be the same as Visit 3.
  - Visit 6 will be scheduled for about 16 weeks after visit 2. This should be about 1 month from this visit (visit 5)
- **Visit 6**
  - You will return any vitamin D that you did not take.
  - Your diary cards, which were completed between visits, will be reviewed with you.
  - You will be asked about
    - Your asthma symptoms

- Visits you made to doctors, hospitals, and other healthcare places
- All medicines you took, including over-the-counter multi-vitamins. (See visit 2 for more information about over-the-counter vitamins.)
- Other medical events that may have happened

- You height and weight will be measured.
- You will be asked to give a urine sample. The sample will be used for a lab test. The test will measure the amounts of 2 substances, calcium and creatinine. If you are a female and have started your periods (meaning you can get pregnant), the urine will also be used for a pregnancy test.
  - If the calcium/creatinine lab value is too high, you will be asked to provide another urine sample. If the lab value is still too high, you will be asked to let us take about ¾ teaspoon of blood from your arm. The blood will be used to test for levels of calcium and vitamin D.
- A blood sample (about 1½ teaspoons total) will be taken from you. Tests will be done for
  - the amount of vitamin D in your blood
  - inflammatory markers
- You will be given an Asthma Control Test. This test is a questionnaire. The questions will be about your asthma symptoms over the previous 4 weeks.
- You will be given new diary cards to fill out over the next month. The study coordinator will explain how to fill out the cards.
- Visit 7 will be schedule for about 20 weeks after visit 2. This should be about 1 month from this visit (visit 6).
  - You will be contacted one time between Visit 6 and 7.
- You will NOT be taking vitamin D after Visit 6.

- **Visit 7**
    - Your diary cards, which were completed between visits, will be reviewed with you.
    - You will be asked questions about your asthma symptoms and other medical events that may have happened since your last visit.
    - You will be asked to initial a form documenting whether you prefer to have this visit's blood sample taken from your arm or taken from a fingerstick.
    - A blood sample will be taken from you. This may be either from your arm or from a finger stick. If blood is obtained from your arm, the volume will be about 1½ teaspoons. If the blood is obtained from a finger stick, the volume will be about ¼ teaspoon. The blood will be sent to a lab. The lab will measure the amount of vitamin D in your blood. If you have agreed to allow a nurse (or other trained medical professional) to collect blood from your arm, then a sample of your blood will also be used to check for blood levels of substances called inflammatory markers.
    - You will be given new diary cards to fill out over the next month. The study coordinator will explain how to fill out the cards.
    - Visit 8 will be scheduled for about 24 weeks after visit 2. This should be about 1 month from this visit (visit 7).
        - You will be contacted at least one time between this visit and your next visit.
- **Visit 8**
    - You will be asked to do the same things at Visit 8 that you were asked to do for visit 7.
    - Visit 9 will be scheduled about 28 weeks after visit 2. This should be about 1 month from this visit (visit 8).

- **Visit 9**
    - Your diary cards, which were completed between visits, will be reviewed with you.
    - You will be asked questions about your asthma symptoms and other medical events that may have happened since visit 8.
    - You will be asked to initial a form documenting whether you prefer to have this visit's blood sample taken from your arm or taken from a fingerstick.
    - A blood sample will be taken from you. This may be either from your arm or from a finger stick. If blood is obtained from your arm, the volume will be about 1½ teaspoons. If the blood is obtained from a finger stick, the volume will be about ¼ teaspoon. The blood will be sent to a lab. The lab will measure the amount of vitamin D in your blood. If you have agreed to allow a nurse (or other trained medical professional) to collect blood from your arm, then a sample of your blood will also be used to check for blood levels of substances called inflammatory markers. The result of the vitamin D level at this time will be given to you so you can discuss with your primary care provider if you should restart taking vitamin D supplements after the study is done.

How long will this study take?

This part (Part 2) of the study will take about 8 months. You will be asked to come to the doctor's office* 8 times after the first visit. The office visits will be about 1 month apart for visits 2, 3, 4, 5, 6, 7, 8, and 9. The last visit, Visit 9, will be about 7½ to 8 months from the time you signed the child assent form.

Visits 2 to 9 will take about 1 hour each. The periodic contacts will take about 15 minutes. The diary cards will take about 10 minutes every day between visits 1 and 6.

Who will see the information about me that is collected?

- The local study team will know your name and have access to your information.
- We will do our best to make sure no one outside the study knows that you are part of the study.

- Your study information will be sent to the lead study team for the IDeA States Pediatric Clinical Trials Network at the University of Arkansas for Medical Science. This information may include protected health information, such as date of birth, but will not include your name. You will be asked to sign a separate HIPAA authorization that will allow us to use protected health information we need to collect to do this study.
- We will take your name off of study information and samples that we collect from you during the study.
- When we share the results of the study, *we* will not include your name.
- There are people who make sure the study is running the right way. These people may see information from the study about you. This information may include information that identifies you. The people that may see this information are:
    - Members of the University of Arkansas for Medical Sciences (UAMS) Institutional Review Board (IRB)
    - Members of the IRB at the institution named on this form
    - OHRP (United States Office of Human Research Protections)
    - Study monitors and other employees of the Data Coordinating and Operations Center (DCOC) for the IDeA States Pediatric Clinical Trial Network (ISPCTN)
    - National Institutes of Health (NIH)
    - Overall-study Principal Investigator (PI)
        - ✓ *INSERT LOCAL CONTEXT IF APPLICABLE*
        - ✓ *Any site-specific groups other than "local IRB," which is already listed, that may access the records or provide oversight, in*
- INSERT LOCAL CONTEXT IF APPLICABLE
- For example:
- "State law requires we tell the authorities if we learn
    - ✓ about possible child or adult abuse
    - ✓ that you might hurt yourself or someone else

Where and how long will my information and samples be kept?

- We will code your information and study samples and limit access to the code. Only people who must have access will be allowed to see the information.
- Blood samples will not be kept. Samples will only be used to do the testing specified for this study.
    - Specifically, the local study team and *<insert other parties that may have access>* will have access to the code for your information.
- We LOCAL CONTEXT: will/will not put a copy of this form in your medical record.

INSERT LOCAL CONTEXT about access to medical records

    - We *will/will not* put other information about you from the study in your medical record. *(Say what information will be put in the participant's medical record.)*

What if I say no, I do not want to be in this study?

- Nothing bad will happen.
- You can still get your medical care at <insert name of institution / location here>.

What happens if I say yes, but change my mind later?

- You can remove yourself from the study at any time.
- Nothing bad will happen to you.
- You can still get medical care at <insert name of institution / location here>.
- If you decide to stop participating in the study, call <insert name of contact here> at < insert phone number of contact here>.

Can I be taken out of the study even if I want to continue?

Yes, the study doctor (or head researcher) can take you out of the study if:

- You do not follow study instructions.
- There is a medical reason that it is not in your best interest to continue.
    - Examples of medical reasons for asking you to stop taking vitamin D are: (1) calcium levels too high in the blood or (2) pregnancy.

- If study personnel say you need to stop taking vitamin D, you may be given a physical exam if the doctor thinks it is necessary.

- The study is stopped for any reason.

If I stop participating in the study, what will happen to any information or samples collected from me in the study?

We will not be able to take your information/samples out of the study after it has started.

Will my information or samples from the study be used for anything else, including future research?

No. Your information and samples will be used only in this study.

Will it cost me anything to be in the study?

The study will not cost you anything. You and your insurer will not be charged for any study-related visits or blood tests. You or your insurance company will be responsible for your regular medical care that is not related to this study.

Will I be paid?

Yes. We will give you $120.00 per visit. This is to pay for your parking and travel ($20.00/visit) and your time ($100.00/visit). You will be paid INSERT LOCAL CONTEXT ON HOW AND WHEN PAYMENTS WILL BE MADE e.g. *cash, gift card, etc.)* at *the end of each visit/end of the study*.

If you change your mind and decide not continue in the study, you will only be paid for the parts you completed.

<Insert local context on reimbursement with regard to collecting name, address, social security number, etc. as it affects study payments/reimbursements and taxable income. For example: "Study payments are taxable income. A Form 1099 will be sent to you and to the Internal Revenue Service if the payments are <insert amount> in a calendar year."

Will being in this study help me in any way?

Being in the study may or may not help you. The results of this study may be used in the future to help other asthmatic children who also have weight that is higher than what is considered as a healthy weight for their height. What we learn may help determine how much vitamin D must be given to such children/teenagers to make sure they have the best vitamin D levels in their blood.

This study may help you get to the healthiest amount of vitamin D in your blood. This could help with bone health or asthma systems, but we do not know if any of these things will happen.

What are the risks of being in this study?

The risks are:

- The risks for this study are no more than what happens in everyday life.
- Someone could find out that you were in the study and learn something about you that you did not want others to know. We will do our best to protect your privacy.
- You could have pain or bruising at the site where blood is collected from your arm.
- It is possible, but very unlikely, that you could bleed too much, get an infection, or faint when blood is taken.
- You may feel uncomfortable about being asked to provide a urine sample.
- You may feel uncomfortable being weighed.
- You may not want to answer certain questions. The questions may make you uncomfortable. You do not have to answer any questions you do not want to answer.
- You will not be taking vitamin D supplements between week 16 (visit 6) and week 28 (visit 9). This is a 3-month gap. Your vitamin D level may decrease during this time. Your vitamin D level will be checked again at week 28 (visit 9) and you will be told your level at that time. Your primary care provider can then decide if vitamin D supplements should be restarted.
- You could get too much vitamin D and have a reaction to the medicine. This would be very unlikely. Vitamin D is very safe and it is hard to overdose on it. However, it is possible that you could have an increase in calcium in your blood and urine. Kidney stones could occur as a result. Accidental poisoning with

doses of vitamin D many times higher than used in this study have been associated with nausea and increased levels of calcium in the blood.

What if I get sick or hurt while I am in this study?

INSERT LOCAL CONTEXT

FOR EXAMPLE:
If you gets hurt when your here for the study, we will help you get the care you needs. This may include first aid, emergency care and/or follow-up care.

- If you are not here and you get hurt or sick, and you think it is because of the study, do these things:
  - ✓ call your doctor or if an emergency, call 911
  - ✓ give your doctor or ER staff
    - the name of this study *(insert name of study)*
    - the name of the head researcher for this study *(insert researcher name)*
    - a copy of this form if you have it
  - ✓ call the head of the study *(insert researcher name and 24 hour phone #)*

Choose from these options:

- This treatment may be billed to you or your insurance company in the normal manner. Normally, no other form of payment is available.

  OR

- *Insert details of agreement negotiated with sponsor*

What are the alternatives to being in this study?

- You do not have to be in this study.
- The alternative is standard of care that you usually get from your doctor.

What if new information comes up about the study?

- We want you to know about anything that may change your mind about your being in the study.

- The researcher will let you know by one of the following methods:
  - calling you
  - sending you a letter, an e-mail, and/or a text message
  - telling you at a follow up visit
- If you choose to stay in the study, you may be asked to sign a new version of the consent form.

Where can I find more information about this clinical trial?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website any time. The NCT number is NCT03686150.

What if I have questions?

- Please call the head researcher of the study *(insert researcher name and phone #),* if you
  - have any questions about this study
  - have questions about your rights
  - feel you have been injured in any way by being in this study
- You can also call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if you
  - have questions about this study
  - have questions about your rights
  - can't reach the study team
  - need to speak to someone not directly involved with this study

What should I do if I want to be in the study?

- Sign this form. We will give you a copy of this form to keep.

By signing the document, I am saying:

- I understand that joining this study is voluntary.

- Someone talked with me about the information in this document and answered all my questions.
- I have been asked if I wish to talk directly to the study doctor.

I know that:

- I can stop participating in any and all parts of the study at any time and nothing bad will happen to me.
- I can call the office(s) that supervises this research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or my rights.
- <Insert LOCAL CONTEXT when applicable. For example: I can also call <i*nsert name of local IRB and phone number when applicable - or delete this bullet>*
- My decision will not change my medical care at *<insert name of institution / location>*.
- I do not give up any of my rights by signing this form.

I agree to be part of this study:

Printed Name of Participant

Signature of Participant | Date (mm/dd/yyyy)

I agree to the optional visit between Visit 2 and Visit 3.

Printed Name of Participant

Signature of Participant | Date (mm/dd/yyyy)

If someone is signing this form for the participant, explain why:

Name of legally responsible person (please print)

Signature of legally responsible person | Date (mm/dd/yyyy)

Relationship to you

Person Obtaining Consent:

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent | Date (mm/dd/yyyy)