

Inhaled Steroids for the Treatment of Early Pediatric Acute Respiratory Distress Syndrome (PARDS), a Randomized Pilot Trial

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PARENTAL PERMISSION TO TAKE PART IN RESEARCH

Simple Study Title: Inhaled steroids for PARDS

Full Study Title: Inhaled steroids for the treatment of early Pediatric Acute Respiratory Distress Syndrome (PARDS), a randomized pilot trial.

Principal Investigator: Alvaro Coronado Munoz, MD; Assistant professor UTHealth

Study Contact: (713) 704-7921 / () -
6431 Fannin St Houston Tx, 77030

The purpose of this study is to see if *Budesonide* can be useful to treat PARDS. If you choose to allow your child to take part in this study, your child could receive either *Budesonide* or normal saline nebulized on the mechanical ventilator to treat PARDS. The total amount of time your child will be in this study is a maximum of 10 days.

There are potential risks involved with this study that are described in this document. Some known risks include worsening on the course of the disease. There may be potential benefits to your child such as improving your child's condition by decreasing the ventilator and decreasing the inflammation in the lungs.

There are alternatives to taking part in this research study, such as continuing with the current care that it does not include any specific treatment for this condition.

Participation in this research study is voluntary. You may choose not to allow your child to take part in this research study or may choose to leave the research study at any time. Your decision will not affect the clinical care your child receives at the University of Texas Health Science Center at Houston (UTHealth) or Memorial Hermann Healthcare System.

If you are interested in participating, please continue to read below.

What is the purpose of this research study?

The purpose of this study is to see how well *Budesonide* works at treating people with Pediatric Acute respiratory distress syndrome (PARDS). This condition is a severe inflammation in the lungs. Children with PARDS have to be in the critical care unit connected to a mechanical ventilator. This study will test the safety of the *Budesonide* to treat PARDS. *Budesonide* has been approved by the Food and Drug Administration (FDA) but not for this specific condition; therefore, it is called an investigational drug. This study is called a pilot study since it will only include a small number of patients and will help us design a larger study with more patients in the future.

Contact: Alvaro Coronado Munoz, MD

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A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This will not include information that can identify your child. After the study has ended, website will include a summary of the results. You can search this website at any time.

Who is being asked to take part in this study?

You are being asked to allow your child to take part in this research study because your child has PARDS. This study is being conducted only in our hospital. About 60 people will take part in the study in this city at UTHealth and Memorial Health System.

What will happen if your child takes part in this study?

If you allow your child to take part in this study your child will be randomized (similar to flipping a coin) to receive *Budesonide* or normal saline. It is not known whether *Budesonide* will be of benefit. Normal saline is currently used in patients with this and other conditions that require mechanical ventilator to help clearing the lung secretions. For this reason, some study participants must receive normal saline to compare. Normal saline is what we call a placebo: a thought to be harmless medication that will allow a careful comparison to study the benefits and side effects of the investigational drug. There is a 50% chance your child will receive *Budesonide* and a 50% chance that your child will receive normal saline. Neither you, your child nor your doctor will know if your child is receiving *Budesonide* or normal saline, as both will look the same.

The only additional test we are going to perform additional to routine standard of care test is samples from the lungs taken out during routine suctioning of your child's airway. These samples will be analyzed for the purpose of the study only and won't affect the treatment of your child. Routine exams, tests, and procedures that need to be done to monitor your child's safety and health will be ordered by the primary team taking care of your child. We will record this information to carefully follow the effects of the study treatment, including preventing and managing side effects.

How long will your child be in the study?

If your child takes part in the study, his or her participation will last for 10 days. We would like to add additional measurements to your child's lung recovery called Pulmonary function tests, free of charge, 90 days after the first day of participation in this study. These measurements will be done by the pulmonary team research team.

What choices does your child have, other than this study?

You may select other options than being in this research study. Currently we allow the patients to recover from PARDS with time and with supportive measure to their breathing and oxygen levels.

What are the risks of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

If you choose to allow your child to take part in this study, there is a risk that *Budesonide* may result in worse outcomes such as lower oxygen levels or longer time on the ventilator.

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There is also a risk that your child could have side effects from the *Budesonide*. These side effects may be worse and may be different than you would get with the usual treatment.

Some of the most common side effects that the study doctors know about are that prolonged use of prolonged steroids are associated to risk of infections like fungal infections. That risk has not been described in the maximum period planned for this study (10 days). Even though *Budesonide* is intended to decrease the inflammation in the lungs and therefore improve the condition of your child any medication delivered to critically ill lungs can worsen their condition prolonging the days that mechanical ventilation is needed. There may be some risks that the study doctors do not yet know about. Children receiving inhaled steroids have less growth by around 0.5 inch than patients that do not receive inhaled steroids. These numbers have been calculated in patients with asthma that receive inhaled steroids for more than 12 weeks. Patients that receive steroids could also have less function on the "adrenal gland" in the body. That gland is in charge of producing our own body's corticoid, called cortisol. There are no studies demonstrating that patients receiving inhaled steroids for short periods of time have that risk.

What are the benefits to taking part in this study?

There is one small pilot study in adult patients with ARDS treated with *Budesonide*. The results were encouraging for reducing inflammation and improving oxygenation but it didn't address the number of days on mechanical ventilator as we are planning to do in our study. We do not know if to the same results will be seen in children with ARDS as they saw with the adults. This study may help the study doctors learn things that may help other people in the future.

Can you stop taking part in this study?

You may decide to stop your child from taking part in the study at any time. To withdraw from the study, please contact Alvaro Coronado Munoz, MD at (████) █████-████ or (713) 704-7921.

Your doctor or the sponsor can stop the study at any time. Your doctor or the sponsor may stop your child's participation in the study if his or her condition worsens, the study is stopped, the study drug is no longer available, your child does not meet all the requirements of the study, or the study is not in your child's best interest. If your child's participation in the study is stopped, your doctor will discuss other options for his or her treatment.

If your child stops participating in this study, the information already collected will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to allow your child to stay in the study.

What happens if your child is injured during the study?

If your child suffers an injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, necessary facilities, emergency treatment, and professional services will be available to your child, just as they are to the general community. You should report any such injury to Alvaro Coronado

Contact: Alvaro Coronado Munoz, MD

Telephone: (713)7047921 / (████) █████-████

Munoz, MD at () - . You will not give up any of your child's legal rights by signing this consent form.

What are the costs of taking part in this study?

The sponsor will pay for the special tests and examinations that are required by this study and not otherwise part of your child's standard medical care.

However, many of the tests, procedures, and exams your child will receive are believed to be part of standard medical care, and may or may not be covered by your medical insurance. If your medical insurance does not pay for your child's care you will be responsible for the cost of the medical care related to your child's condition including laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures.

If you receive a bill that you believe is related to your child's taking part in this research study, please contact Alvaro Coronado Munoz, MD () - with any questions.

How will privacy and confidentiality be protected?

Your child's privacy is important and your child's participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UTHealth or Memorial Hermann Healthcare System to use and disclose (release) your child's health information. The health information that we may use or disclose for this research includes your child's age, diagnosis, days of illness, the indications for mechanical ventilator and laboratory results decided by the primary team. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

We will also collect respiratory sample that are routinely collected in patients with your child's condition. We will analyze these samples in the UTHealth Pediatric Critical Care Laboratory for markers of inflammation in the lungs. These results will be only used for the research study but won't affect the clinical care of your child. These samples are routinely collected in patients with your child condition and there are no additional risks to your child when we collect these samples.

Personal identifiers such as your child's name and medical record number will be removed from the information and samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional permission.

People who receive your child's health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your child's health information and may share your child's information with others without your permission, if permitted by laws governing them. Your child will not be personally identified in any reports or publications that may result from this study. If all information that does or can identify your child is removed from your child's health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

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Representatives of the organizations listed below will see your child's name and other personal identifiers when they review your child's research records and medical records for the purposes of verifying study data:

- Representatives of UTHealth and/or Memorial Hermann Health System
- Representatives from the U.S. Food and Drug Administration (FDA)
- Representatives of the sponsor of this research including contract research organizations
- Companies engaged with the UTHealth for the commercialization of the results of the research study

Please note that you do not have to sign this Authorization, but if you do not, your child may not participate in this research study. UTHealth and Memorial Hermann Health System or Harris Health System may not withhold treatment or refuse treating your child if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about your child as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact Alvaro Coronado Munoz, MD in writing at 6431 Fannin St [REDACTED] Houston Tx 77030.

This Authorization will expire 15 years after the end of the study.

Whom can you contact if you have questions about the study?

If you have questions at any time about this research study, please feel free to contact Alvaro Coronado Munoz, MD at ([REDACTED]) [REDACTED]-[REDACTED], as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at (713) 500-7943.

What will happen when my child becomes a legal adult?

If your child will reach the legal age of majority (18 in the state of Texas) and is able to provide his or her own consent while enrolled as a participant in this study, the study team will contact him or her to obtain his or her adult consent.

Contact: Alvaro Coronado Munoz, MD

Telephone: (713)7047921 / ([REDACTED]) [REDACTED]

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to allow your child to take part in this research study. Make sure that all your questions have been answered. If you decide to allow your child to take part in this research study, a copy of this signed consent form will be given to you.

Name of Child

_____ Name of Parent/ Guardian	_____ Relationship to Child	_____ Signature	_____ Date
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_____ Name of Person Obtaining Consent	_____ Signature of Person Obtaining Consent	_____ Date
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