Document Cover Page

Study Title: Comparison Study of LMX4 Cream Versus J-Tip Needle Free Injection System with Lidocaine for In-Office PAT for Clubfoot

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VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	A Randomized, Comparison Study of L.M.X.4 Cream versus J-Tip Needle-Free Injection System with Lidocaine in Children Undergoing In-Office Percutaneous Achilles Tenotomy for Clubfoot
Version Date:	6/1/2021
PI:	Jeffrey Martus, MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

Your child is being asked to take part in this study because they been diagnosed with congenital idiopathic clubfoot. At Vanderbilt, we use the Ponseti method to treat congenital idiopathic clubfoot. The Ponseti method is a safe and effective treatment for clubfoot that decreases the need for more extensive surgery. This treatment method involves weekly stretching of the foot followed by a long-leg cast. The weekly castings usually correct most parts of the clubfoot deformity within 6 weeks, but patients may still have an abnormally tight Achilles tendon following casting. To correct this problem a procedure called a percutaneous tendoachilles tenotomy is performed. To perform the tenotomy, an anesthetic cream is applied to the skin behind the child's ankle for 30 minutes. After 30 minutes has passed, the cream is removed and the doctor uses a small scalpel to cut through the skin and cut the achilles tendon.

The purpose of this study is to investigate whether a new method of numbing the incision site, a needle-free xylocaine injection system, provides better pain relief to the infant during the procedure than the anesthetic cream we normally use. If you choose to allow your child to participate in this study, your child will be randomized to receive either anesthetic numbing cream and a placebo needle-free injection or a placebo cream and an anesthetic needle-free injection prior to the tenotomy procedure. We will also monitor your child's pain and temperament throughout the weekly casting visits, on the tenotomy procedure date and for the one month following the procedure. The time you would normally spend at some of these visits may be extended due to your child's participation in the study. You will be asked to

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complete study surveys 1 week prior to the tenotomy procedure (2-3 minutes), and then again at 1, 7, 14 and 21 days after the tenotomy procedure (about 5-10 minutes).

It is unknown if your child will benefit from taking part in this study. If your child is assigned to the needle-free injection system, it may provide greater pain relief to your child during the procedure. The xylocaine used in the needle-free injection system, may cause a rash, redness, irritation, or swelling at the site of application. If your child is assigned to the anesthetic cream, the cream may cause rash, redness, irritation, or swelling at the site of application.

There will be no additional costs to take part in this study.

The needle-free injection system, called J-Tip, is FDA cleared.

We will be enrolling 58 patients in this study.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Study Purpose

You child is being asked to take part in this study because they been diagnosed with congenital idiopathic clubfoot. At Vanderbilt, we use the Ponseti method to treat congenital idiopathic clubfoot. The Ponseti method is a safe and effective treatment for clubfoot that decreases the need for more extensive surgery. This treatment method involves weekly stretching of the foot followed by a long-leg cast. The weekly castings usually correct most parts of the clubfoot deformity within 6 weeks, but patients may still have an abnormally tight Achilles tendon following casting. To correct this problem a procedure called a percutaneous tendoachilles tenotomy is performed. To perform the tenotomy, an anesthetic cream is applied to the skin behind the child's ankle for 30 minutes. After 30 minutes has passed, the cream is removed and the doctor uses a small scalpel to cut through the skin and cut the achilles tendon. The purpose of this study is to investigate whether a new method of numbing the incision site, a needle-free xylocaine injection system, provides better pain relief to the infant during the procedure than the anesthetic cream we normally use. The needle-free injection system, called J-Tip,

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uses compressed CO2 instead of a needle to push xylocaine into the skin, which provides local anesthetic at the site of application in less than one minute.

Your child does not have to be in this research study. You may choose for your child to not be in this study and get other treatments without changing your child's healthcare, services, or other rights. You can stop your child from being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want your child to be in this study. Your child's medical record will contain a note saying they are in a research study and may contain some research information about your child. Anyone you authorize to receive your child's medical record will also get this information

Side effects and risks that you can expect if your child takes part in this study:

Side Effects of Xylocaine and Lidocaine
Xylocaine and Lidocaine can cause rash, redness, irritation, or swelling at the injection site (J-Tip injection treatment) or site of the application.

Breach of Confidentiality Risk
Every attempt will be made to keep your child's protected health information private. Most data will be recorded in a Vanderbilt REDCap database. Any physical study forms will be kept in a locked cabinet in the principal investigator's office. All study data will be maintained for 6 years. Data will then be archived, and all physical study forms will be disposed of in confidentiality shred-it bins.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: If it is determined that the utilization of the J-Tip needle-free injection system with 1% Xylocaineis equal to or more effective at reducing pain in infants undergoing a tenotomy than L.M.X.4 cream (4% Lidocaine cream that is applied directly to the skin) is, the potential benefits of this study may include: better pain management in infants undergoing a tenotomy in the future. In addition, the reduction in the amount of time required to numb the surgical area from 30 minutes with L.M.X.4 cream to 1-2 minutes with a J-Tip needle-free injection would decrease the overall length of the infant's visit and cost of procedure. This would increase the quality, safety and value of the procedure.

Procedures to be followed:

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Enrollment Visit (Research portion will take 30 minutes)
At the study enrollment visit, you will be asked to review this consent form. If you agree to allow your child to take part in this study, we will collect information about your child from you and from his/her medical record. Your child's doctor will also record the shape of the foot.

Weekly Casting Visits (Research portion will take 2 minutes)
As part of your child's routine care, they will undergo casting weekly. As part of the research study, your child will wear a pulse oximeter on their hand, covered by a mitten if needed, that will measure their heart rate and oxygen saturation. A Certified Child Life Specialist will be in the room with a research assistant and they will assess your child's pain and temperament at 3 different points of the visit (before cast, the start of casting and the end of casting).

At the final casting visit, we will ask you to complete a temperament questionnaire about your child. Your child's doctor will also determine if they require a tenotomy procedure. If your child does not require a tenotomy procedure, they will be withdrawn from the study. If they do require a tenotomy procedure, your child will be randomized to one of two anesthetic options for the tenotomy procedure. Being randomized means that your child will be put in a group by a chance process, like flipping a coin. We are using randomization because it is not clear at the present time, which anesthetic option is better. Your child's chance of receiving either anesthetic option is equal.

The two anesthetic treatment options are:

- **L.M.X.4 cream (liposomal lidocaine) with J-Tip needle-free injection of saline**

  or

- **Placebo cream with J-Tip needle-free injection of 1% Xylocaine**

  A placebo is a substance that has no therapeutic effect and is used as a control in testing.

Tenotomy Visit

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Your child will receive pain control for the tenotomy based on the study group to which they were randomized. The following procedures will take place:

- * Your child will be positioned on the treatment table.
- * The randomized topical cream (L.M.X.4 or placebo cream) will be applied to your child's ankle for 30 minutes.
- You will be asked to consent to the tenotomy procedure.
- * The topical cream will be removed from your child's foot (routine care).
- You will be asked to leave the room. This is not part of the study, but part of routine care.
- Your child will stay with the healthcare staff.
- * The J-Tip needle-free injection will occur with the randomized solution (1% Xylocaine or saline).
- * Following J-Tip injection there will be a 3-minute break. The baby will be calmed during this time.
- * The tenotomy will be performed.
- * A cast will be applied.

*** Your child's pain will be assessed, and their heart rate and oxygen saturation level will be recorded.**

Post-Tenotomy

Surveys (5-10 minutes)
You will be asked to complete a survey 1, 7, 14 and 21 days after your child's procedure. The survey will ask you about your child's pain level, irritability, doses of Tylenol administered and any other problems that your child may be having due to the procedure.

Clinic Visit around 21 days after Tenotomy (Research portion will take 10 minutes)
During this routine care visit, your child will be assessed for complications related to their procedure. We will ask you to complete a survey regarding quality of care, post-procedure care and your child's pain level.

Payments for your time spent taking part in this study or expenses:

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None

Costs to you if your child takes part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case your child is injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case your child is injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact **Jeffrey Martus, MD** at **615-343-5875** or the research coordinator at 615-322-4506.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take your child out of this study:

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Your child may be removed from the study if it is determined they do not need to undergo a tenotomy after weekly casting.

What will happen if you decide to stop allowing your child to be in this study?

If you decide to stop being part of the study, you should tell your study doctor.

Clinical Trials Registry:

A description of this clinical trial will be available on 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 Web site at any time.

Confidentiality:

During this study every attempt will be made to keep your child's protected health information (PHI) private. Most study data will be maintained in a Vanderbilt REDCap database. Vanderbilt Redcap is a secure, web-based application for building and managing online databases. The data obtained and stored in Redcap will only be accessible by research personnel. Any data sent to non-key study personnel for statistical analysis will be de-identified (dates will be shifted using a Redcap feature). Study personnel will use VUMC Box to share research documents. The VUMC Box study folder will only be accessible by research personnel. Any physical study forms (ex. consent documents, case report forms) will be kept in a locked cabinet in the principal investigator's office. All study data will be maintained for 6 years following study completion. Following this 6 year period, the Redcap database will be archived and all physical study forms will be disposed of in shred-it confidentiality bins provided by VUMC.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

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Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
There are no plans to share the results of this research with you.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your child's information be used or shared?

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Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to allow your child to take part in this research study, it will not affect your child's treatment, payment or enrollment in any health plans or affect your child's ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to allow my child to take part in this study.

Date _____ Signature of parent/legal guardian 1 _____

Consent obtained by:

Date _____ Signature _____

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Time: _____ _____
Printed Name and Title