AmnioFix® INJECTABLE

Is this clinical trial registered with the FDA? Yes.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. The study title is: A Phase 3, Prospective, Double-Blinded, Randomized Controlled Trial of the Micronized dHACM Injection as Compared to Saline Placebo Injection in the Treatment of Achilles Tendonitis.

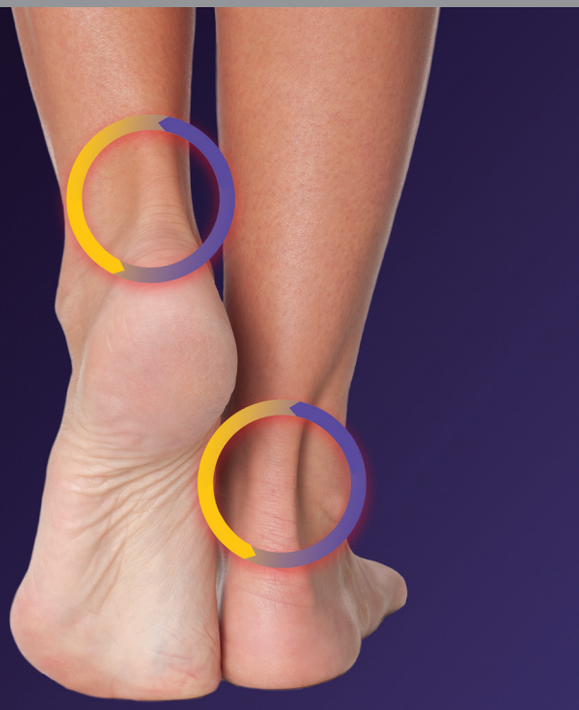
Additional Information

Before enrolling in a clinical trial, you will undergo the informed consent process. At this time, the investigator and study staff will explain the purpose of the trial, its expected benefits, possible risks or side effects, and what your role will be. Please feel free to ask the study staff any additional questions you may have!

Why AmnioFix Injectable?

Amniotic membrane products, including AmnioFix Injectable, have been the subject of many scientific publications evaluating its use in wound care, orthopedics, sports medicine, and a multitude of other surgical applications. The amniotic membrane tissue for AmnioFix Injectable is donated by healthy, consenting mothers undergoing scheduled Caesarean sections. The amniotic membrane is the cover surrounding the baby during pregnancy, and is typically discarded after the baby is born. The recovery of the membrane does not affect the baby or the delivery process. All tissue donors are tested for infectious diseases, similar to the testing done for blood donation. The amniotic membrane then undergoes a validated proprietary process to thoroughly cleanse and preserve the tissue.

HAVE YOU BEEN DIAGNOSED WITH **ACHILLES TENDONITIS?**



You may be eligible to participate in a clinical research study

Ask your doctor if AmnioFix® Injectable is right for you

AmnioFix® INJECTABLE

What is AmnioFix Injectable?

AmnioFix Injectable is a human tissue allograft made from part of the human placenta, the amniotic membrane. Amniotic membrane has been used to treat painful conditions in the foot as well as hard-to-heal wounds and has been used clinically in various forms for almost 100 years. AmnioFix Injectable contains natural components, called growth factors, that may help promote and speed up the body's normal healing process.

Growth factors are powerful agents that our bodies produce to signal cells to come to the target site, help the site to heal, and help your own cells restore the damaged tissue.

AmnioFix Injectable does not contain live stem cells and is not categorized as a stem cell injection. AmnioFix Injectable allografts are procured and processed in the United States according to the standards and/or regulations established by the American Association of Tissue Banks (AATB) and the United States Food and Drug Administration (FDA).

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Is AmnioFix Injectable Right for Me?

You and your doctor may consider AmnioFix Injectable an option if:

- You have been diagnosed with Achilles Tendonitis
- Conservative treatments such as anti-inflammatories, physical therapy and bracing have not provided relief of symptoms

Treatment Information

How do I prepare for an injection? You will be scheduled for an evaluation and consultation to determine if AmnioFix Injectable is a suitable treatment option for you. You will be randomly selected to receive either AmnioFix Injectable or a saline placebo. The injection process is very short and is generally performed during an office visit.

What happens after my injection? Initially, the procedure may cause pain at the injection site. The site may also appear red and be tender to the touch. Your physician may prescribe some rehabilitation exercises, as well as other post-treatment care. You will additionally be asked to complete follow-up questionnaires and return for follow-up visits to assess your pain, physical activities, and quality of life. If you have any questions about your treatment, please consult your doctor.

How much will it cost? There are no additional costs associated with participation in the study. The sponsor of the study will provide AmnioFix Injectable to you free of charge and you will not be billed for it if you are randomized to receive it. You will also be provided, free of charge, a cam boot, a heel lift, and you will be seen routinely for evaluation according to the study schedule. Procedures (such as X-ray) that are done only for the study will not be billed to you or your insurance company.

How often will I be seen? You will return to the clinic 6 times after your treatment visit, at 30 days, 60 days, 3 months, 9 months and 12 months after the initial injection procedure. Each visit will last about 30 minutes. As part of the study you will also complete a pain diary. The diary will be a text message or email containing two questions each time. You will need to have daily access to text messages with a smartphone or email in order to participate. You will complete a total of thirteen Patient Pain Diary entries during the course of the study.

Is AmnioFix Injectable safe? Tissues used to produce AmnioFix Injectable have been screened for communicable diseases, and additionally the product is terminally sterilized to further enhance patient safety.

Are there side effects? AmnioFix Injectable has been used in a number of clinical trials, and the complication rate associated with the product is low. The most common complications include pain, redness and/or swelling at the injection site. As with all biological implants, an absolute guarantee of tissue safety is not possible. Strict donor screening, laboratory testing, and sterilization of the product significantly reduce the risk of any disease transmission.