



ISTOL

Are you battling sores on your fingertips?...

A Clinical Trial Opportunity for Adults with Scleroderma

DISTOL-1 Trial

Digital Ischemic Lesions in Scleroderma Treated with Oral Treprostinil Diethanolamine: A randomized, double-blind, placebo-controlled, multicenter research study

Purpose of the Study

The purpose of this research study is to determine if treprostinil diethanolamine (UT-15C SR) is effective at healing your digital ulcers. Digital ulcers (ulcers on your finger tips) often develop in people with a condition called systemic sclerosis (scleroderma). We are recruiting males and females, 18 years and older, with systemic sclerosis who have ulcers on their fingertips.

This is a 20 week research study comparing treprostinil diethanolamine to placebo (sometimes called a fake pill). During the study you will return to the clinic every 5 weeks for your doctor to evaluate your digital ulcers and to complete study questionnaires. All evaluations and medications for this study are provided without cost to participants. The risks and benefits of this study will be explained to you thoroughly before you agree to participate.

Treprostinil diethanolamine is an analog of prostacyclin. Prostacyclin is a naturally occurring substance produced by the cells of blood vessels that increases blood flow. Treprostinil diethanolamine (UT-15C SR) is an investigational drug for digital ulcers caused by systemic sclerosis or scleroderma. An investigational drug is one that has not been approved by the Food and Drug Administration (FDA) or other agency as a prescription or over-the-counter drug. This study drug is contained in a tablet that is taken by mouth and is released over an extended period of time (sustained release, or SR).

Am I eligible for the DISTOL-1 research study?

You may be eligible for the DISTOL-1 Study if you...

- ...have been diagnosed with systemic sclerosis (SSc) as defined by American College of Rheumatology (ACR) criteria.
- ...are greater than 18 years at time of study screening.
- ...have at least one active digital ulcer (open wound on the end of your finger).

- ...are willing to use birth control if you are a woman of child-bearing potential.

You probably are *not* eligible if you ...

- ... have a diagnosis of pulmonary arterial hypertension (PAH).
- ...weigh less than 40 kg (88 lbs).
- ...have another connective tissue disease, such as rheumatoid arthritis or lupus.
- ...use tobacco, or have in the past 6 months.
- ...use bosentan for your digital ulcers.

For more information, visit:
www.clinicaltrials.gov
Study Identifier: **NCT00775463**

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United Therapeutics Corp.

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