

Interested in joining the Baseline Skin Study? Feel free to share this summary of key study details with your physician.

The goal of the study is to evaluate a topical ointment therapy, applied twice daily, for the treatment of common symptoms of Stasis Dermatitis.

## Study design

### 14-week study

Including screening, 6-week treatment period, and follow up

# 92 participants

Compression therapy permitted if already in use at time of study enrollment.

#### Two intervention groups

Group 1 (N=46): Study ointment, 2% (w/w) BID for 43 days Group 2 (N=46): Vehicle BID for 43 days

## Study type

Phase 2a, randomized, double-blind, vehicle-controlled, parallel-group proof-of-concept study

## Participants receive

- · Use of a smartphone for study activities
- Dedicated Baseline [study coach] to answer questions
- · Ability to participate from home
- Up to \$300 compensation

# Key screening criteria

#### Inclusion

- · At least 45 years of age
- Have common symptoms of Stasis
   Dermatitis (including itchiness, swelling, and redness on the legs) or a known diagnosis of Stasis Dermatitis
- Had an inadequate response to emollient treatment
- Stable concurrent medical condition(s [e.g. heart disease, kidney disease, COPD, obesity]

#### **Exclusion**

- Clinically significant active or potentially recurrent dermatological conditions that overlap Stasis Dermatitis
- Active venous stasis ulceration on either lower extremity
- Current infection or suspected infection of the lower extremities in the 2 months prior to screening
- History of angioedema or anaphylaxis to topical products

See clinicaltrials.gov for more details on the study.

For additional questions or general information regarding the study, you can check out our study page at projectbaseline.com/skin or contact:

# **Baseline Skin Study Team**

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