



BASELINE SKIN STUDY

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

The Baseline Skin Study is sponsored by Pfizer, who is providing funding to Verily Life Sciences LLC to conduct the study. The goal of the study is to evaluate the effects of an investigational ointment versus a vehicle ointment over time to potentially treat Stasis Dermatitis.

Study design

14-week study

Including screening, 6-week double-blind 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% (with active ingredient) BID for 43 days
Group 2 (N=46): Vehicle ointment (without active ingredient) 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 Study Coach to guide participation from start to finish
- Home visits by a Visiting Clinician (RN other licensed professional)
- Study participation from home
- Up to \$300 compensation

Key inclusion criteria

- At least 45 years of age
- Diagnosis of Stasis Dermatitis, or symptoms consistent with diagnosis of Stasis Dermatitis, with inadequate response to treatment.
- Mental and physical status that allows for ability to perform study activities such as study ointment application to lower legs and the use of an internet-enabled device (smartphone) to complete questionnaires.

Key exclusion criteria

- 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
- Any unstable concurrent medical condition associated with lymphedema, venous insufficiency and venous hypertension

See <u>clinicaltrials.gov</u> for more details on the Baseline Skin Study, Protocol Number C3291038.

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

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