

A clinical study to evaluate the safety and effect of PRA-523, an investigational drug, compared to a drug with no active ingredient for the treatment of itch caused by atopic dermatitis

Submission date 15/01/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 21/01/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 13/04/2026	Condition category Skin and Connective Tissue Diseases	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

The study aims to evaluate whether PRA-523 is safe, how it is metabolized by the body, and whether it improves itch symptoms due to atopic dermatitis as compared to placebo.

Who can participate?

Adults 18-69 years with itchy skin from atopic dermatitis/eczema may participate in this study.

What does the study involve?

The study involves attending up to 9 in person visits to the clinical center over the course of approximately 11 weeks. Participants in the first phase of the study will be required to stay overnight in the clinic twice during the study.

All study participants will be required to complete a daily tracking diary of itch symptoms and study drug usage and will self-administer a topical cream at home for 28 days. This study is placebo-controlled, meaning that some participants will receive the study drug, and some will receive a look-alike drug that will not contain the active ingredient. You and your study doctor will not know which you have received.

What are the possible benefits and risks of participating?

Participants assigned to active treatment may experience relief of their pruritus symptoms during the study, but this is not guaranteed. In addition, participation will help researchers better understand the potential improvement of atopic dermatitis symptoms caused by the drug being studied and its overall safety. Risks associated with participation include those associated with study evaluations such as blood draws and ECGs. Risks associated with the study drug include local skin reactions at the application site.

Where is the study run from?

The study is being run at three clinical centers in New Zealand in Auckland (2) and Christchurch (1) .

When is the study starting and how long is it expected to run for?

February 2026 to March 2027

Who is funding the study?

The study is being funded by Praeventix, Inc., a biopharmaceutical company who is developing PRA-523.

Who is the main contact?

cohara@praeventix.com

Contact information

Type(s)

Public

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Additional identifiers

Study information

Scientific Title

A double-blind, randomized, adaptive, vehicle controlled first in-human phase 1-2a trial to determine the safety, pharmacokinetics, and efficacy of PRA-523 against pruritus secondary to atopic dermatitis

Study objectives

The study aims to determine PRA-523's safety, tolerability, pharmacokinetic profile and efficacy as compared to placebo

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 22/12/2025, Central Health and Disability Ethics Committees (PO Box 5013, Wellington, 6140, New Zealand; +64 800 400 569; hdec@health.govt.nz), ref: 2025 FULL 24409

Primary study design

Interventional

Study design

Double-blind, randomized, adaptive, vehicle controlled first-in-human phase 1-2a trial

Study type(s)

Efficacy, Safety, Treatment

Health condition(s) or problem(s) studied

Pruritus secondary to atopic dermatitis

Interventions

Participants will be randomized to the active drug or a placebo with no active drug (2:1) via an IRT System and will apply the assigned study drug twice a day for up to 28 days. After the completion of dosing, the participants will be followed up for an additional 14 days. Participants in the Phase 1 portion of the study will also undergo PK evaluations at 2 study visits.

Intervention Type

Drug

Phase

Phase I/II

Drug/device/biological/vaccine name(s)

PRA-523, Vehicle

Primary outcome(s)

1. Number of TEAEs possibly, probably, or definitely related to PRA-523 vs. vehicle per participant measured using Adverse Events Reporting / patient notes for Vital Signs, ECG, and Laboratory Parameters (Biochemistry, Haematology and Urinalysis) at Day 1 (Baseline) to End of Study (TEAEs), and from Day 1(baseline) to each scheduled assessment (Vitals, ECG, Lab Parameters)

Key secondary outcome(s)

1. Standard PK parameters derived from plasma concentrations of PRA-523 following dosing measured using Pharmacokinetics Assay to detect PRA-523 in plasma at Day 1 (Baseline), Day 28, Day 30, Day 31

Completion date

31/03/2027

Eligibility

Key inclusion criteria

1. Age between 18-69 years
2. Atopic dermatitis, diagnosed for at least the previous 6 months
3. Current atopic dermatitis investigator's global assessment (VIGA-AD) ≥ 2 at screening and baseline (Day 1).
4. Body surface area affected by AD 2-25% at baseline and screening, excluding palms, scalp, soles, genitals and intertriginous areas
5. Minimum Peak pruritus numeric rating scale (PP-NRS) at screening and baseline (Day 1) and averaged over the run-in period.
6. Use of effective contraception for those of reproductive potential or those with partners of reproductive potential

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

69 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Unstable course of atopic dermatitis, in the opinion of the Investigator
2. Use of oral antihistamines (H1 and/or H2 blockers); e.g. diphenhydramine, loratadine, fexofenadine, cetirizine, famotidine) within 14 days of first dose.
3. Use of other (non-antihistamine) nonbiologic systemic treatment for atopic dermatitis (e.g. cyclosporine, methotrexate) including ultraviolet light therapy, for atopic dermatitis in 2 months prior to baseline
4. Use of biologic therapies for atopic dermatitis within 3 months of screening
5. Treatment with topical medication for AD within 14 days prior to Day 1.
6. Emollient use between Day -1 (day before first dose) and Visit 6 (last day of dosing) on affected skin identified for treatment at Baseline (or subsequent visits). Stable bland emollient use is permitted during the treatment period on skin areas untreated with IMP.
7. The presence of a skin condition which, in the opinion of the investigator, would interfere with the interpretation of the results or conduct of the trial, including, but not limited to keloids, hypertrophic scars, or other clearly defined etiology for pruritus other than atopic dermatitis

Date of first enrolment

10/04/2026

Date of final enrolment

30/11/2026

Locations

Countries of recruitment

New Zealand

Study participating centre

New Zealand Clinical Research (NZCR)

Grd floor, 3 Ferncroft St
Grafton, Auckland
New Zealand
1010

Study participating centre

Optimal Clinical Trials-Auckland

Level 2, 97 Grafton Road
Grafton, Auckland
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Study participating centre
Optimal Clinical Trials - Christchurch
Level 2, 264 Antigua Street
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Sponsor information

Organisation
Praeventix, Inc.

Funder(s)

Funder type
Not defined

Funder Name
Praeventix, Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available