ISRCTN37934199 https://doi.org/10.1186/ISRCTN37934199

Study evaluating the effects of a metabolite-based soap on skin hydration and sensitive skin symptoms in healthy adults

Submission date
17/03/2026

Recruitment status
No longer recruiting

Registration date
21/05/2026

Overall study status
Completed

Last Edited
21/05/2026

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Sensitive skin is commonly associated with dryness, irritation, and reduced skin barrier function. Traditional cleansers may disrupt skin lipids and microbial balance. A new metabolite-based soap containing fermentation-derived postbiotic metabolites has been developed to help support skin barrier health and microbial balance.
This study aims to evaluate whether regular use of this soap improves skin hydration, reduces symptoms of sensitive skin, and improves skin barrier function compared with a neutral control soap.

Who can participate?
Healthy adults aged 20 to 45 years with self-reported sensitive skin and Fitzpatrick skin types II–V

What does the study involve?
Participants will first complete a 2-week washout period using a neutral cleanser. They will then be randomly assigned to one of two sequences to receive either the metabolite-based soap or a control soap. Each soap will be used for 4 weeks, with a 3-week washout period between treatments. Participants will wash their face and forearm twice daily with the assigned soap. During clinic visits, researchers will measure skin hydration, skin barrier function, sensitive skin symptoms, skin microbiome composition, and biochemical markers related to skin lipids and cellular energy.

What are the possible benefits and risks of participating?
Participants may experience improvements in skin hydration and reduced skin sensitivity. Risks are expected to be minimal and may include mild skin irritation, dryness, or temporary discomfort related to the cleansing products.

Where is the study run from?
Innovation Labo Sciences Co., Ltd (Japan)

When is the study starting and how long is it expected to run for?
October 2025 to February 2026

Who is funding the study?
Japanese Medical Institute

Who is the main contact?
Dr Taro Hirata, coordinate@medica-labs.jp

Contact information

Type(s)
Scientific

Contact name
Dr Yuki Ikeda

Contact details
Shintomi HJ bldg 5F
1-12-7 Shintomi
Chuo-ku
Japan
104-0041
+81 (0)335525335
development@innovationlabo.com

Type(s)
Public

Contact name
Mrs Aki Honda

Contact details
Shintomi HJ bldg 5F
1-12-7 Shintomi
Chuo-ku
Japan
104-0041
+81 (0)335525335
tokyo@innovationlabo.com

Type(s)
Principal investigator

Contact name
Dr Taro Hirata

Contact details
14-5 Kusunokichō, Nishi-ku
Yokohama-shi

Kanagawa-ken
Yokohama
Japan
220-0003
+81 (0)335525335
coordinate@medica-labs.jp

Additional identifiers

Study information

Scientific Title
A randomized double-blind two-sequence two-period crossover clinical trial in healthy adults with sensitive skin comparing a metabolite-based soap with a neutral control soap to evaluate effects on skin hydration, skin barrier function, sensitive skin burden, microbiome composition, lipid profile, and cellular energy markers

Study objectives
To determine whether four weeks of use of a metabolite-based soap improves facial skin hydration compared with a neutral control soap in healthy adults with sensitive skin.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/09/2025, Japanese Society of Anti-Aging Nutrition (JAAN) Ethics Review Committee (Ginza, Tokyo 6-6-1, Chuo-ku, 104-0061, Japan; +81 (0)3 3552 5277; coordinator@jaan.jp), ref: JAAN/JMI BTR RCT AP-21

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Crossover

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied

Sensitive skin

Interventions
Participants are enrolled in a randomized, double-blind, two-sequence, two-period crossover clinical trial comparing a metabolite-based soap (test product) with a neutral control soap.

Participants are randomly assigned in a 1:1 ratio to one of two treatment sequences. Block randomisation is used to
allocate participants to each group:
Sequence AB: metabolite soap followed by control soap
Sequence BA: control soap followed by metabolite soap

Each treatment period lasts 4 weeks, separated by a 3-week washout period using a neutral cleanser. A 2-week washout phase using the neutral cleanser is performed before baseline.

Participants wash the face and volar forearm twice daily with the assigned soap during each treatment period.

The metabolite-based soap contains a blend of postbiotic metabolites derived from fermentation of lactic acid bacteria. The control soap has an identical base formulation but does not contain the metabolite complex.

Clinical and mechanistic assessments are performed at baseline and at the end of each treatment period and include measurements of skin hydration, transepidermal water loss, sensitive skin questionnaire scores, microbiome analysis, and biochemical markers. Compliance is monitored through participant diaries and product weight verification.

Intervention Type
Other

Primary outcome(s)
1. Skin hydration measured using a Corneometer CM825 at day 0 and day 28 of period 1 and period 2

Key secondary outcome(s))
1. Transepidermal water loss (TEWL) measured using a Tewameter TM300/610 at day 0 and day 28 of period 1 and period 2

2. Sensitive skin symptoms measured using the Burden of Sensitive Skin (BoSS) score at day 0 and day 28 of period 1 and period 2

Completion date
05/02/2026

Eligibility

Key inclusion criteria
1. Healthy male or female adults aged 20–45 years
2. Fitzpatrick skin types II–V
3. Self-reported sensitive skin with BoSS ≥“mild” at screening
4. Stable skincare and lifestyle habits for ≥4 weeks prior to enrollment

5. Agreement to avoid use of any other facial or forearm cleansers, topical actives, or cosmetics during the study
6. Willingness to provide written informed consent

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
20 years

Upper age limit
45 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Presence of chronic skin disorders (eczema, psoriasis, dermatitis)
2. Use of systemic or topical antibiotics, corticosteroids, or retinoids within 8 weeks before baseline
3. Cosmetic procedures (peeling, laser, microneedling) within 3 months
4. Known allergy or hypersensitivity to soap ingredients
5. Pregnancy or breastfeeding
6. Participation in another clinical study within the preceding 3 months

Date of first enrolment
06/10/2025

Date of final enrolment
23/10/2025

Locations

Countries of recruitment
Japan

Sponsor information

Organisation
Japanese Medical Institute

Funder(s)

Funder type

Funder Name
Japanese Medical Institute

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available