ISRCTN11405020 https://doi.org/10.1186/ISRCTN11405020

Clinical evaluation of cosmetic ingredients for whitening and freckle-removing efficacy using a UV-induced pigmentation model

Submission date
29/10/2025

Recruitment status
No longer recruiting

Registration date
30/10/2025

Overall study status
Completed

Last Edited
30/10/2025

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
This study is looking at how well 17 common cosmetic ingredients work to lighten dark spots on the skin. These ingredients are often used in products that claim to whiten skin or remove freckles. The goal is to find out which ones are most effective at reducing skin pigmentation.

Who can participate?
Healthy men and women aged 18 to 60 can take part, as long as they have fair, even skin and no history of skin conditions like eczema or psoriasis, or any known allergies.

What does the study involve? (for participants)
If you join the study, small areas of skin on your back will be darkened using UV light to create spots similar to sun damage. You'll then apply one of the test products (or a placebo) to these areas twice a day for four weeks. Researchers will check how much lighter the skin becomes using a special device and by having a dermatologist look at it.

What are the possible benefits and risks of participating?
By taking part, you'll be helping researchers learn which ingredients are most effective for skin whitening and freckle removal. This could lead to better cosmetic products in the future. Risks are expected to be low, but there may be some temporary skin irritation or sensitivity from the UV light or the products used.

Where is the study run from?
Shenzhen Hujia Technology Co., Ltd. (China)

When is the study starting and how long is it expected to run for?
August 2025 to December 2025.

Who is funding the study?
Shenzhen Hujia Technology Co., Ltd. (China)

Who is the main contact?
Guoying Li, caohejingschc@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mrs Guoying Li

ORCID ID
https://orcid.org/0009-0002-0313-2706

Contact details
Floor 18, Fenglin International Center, Building A
380 Fenglin Road, Xuhui District
Shanghai
China
200032
+86 17321318135
caohejingschc@163.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2025GX021FA01

Study information

Scientific Title
Randomised, double-blind, controlled clinical trial to evaluate the efficacy of 17 common whitening cosmetic ingredients at their maximum permitted concentrations

Study objectives
The primary objective is to evaluate and compare the whitening efficacy of 17 cosmetic ingredients in a UV-induced pigmentation model, while secondary objectives include providing data for ingredient selection, revealing efficacy differences, and monitoring adverse events.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/08/2025, Shanghai Ethics Committee For Clinical Research (Floor 18, Fenglin International Center, Building A, Shanghai, 200032, China; +86 17321318135; congyi.song@scrcnet.org), ref: SECCR2025-192-01

Study design
Randomized double-blind controlled interventional cosmetic efficacy trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Hyperpigmentation, skin whitening efficacy

Interventions
Intervention type: Topical application of cosmetic whitening emulsions

Intervention details:
17 whitening cosmetic emulsions tested:
Kojic acid (0.7%), Arbutin (2%), Niacinamide (3%), Vitamin C (7%), Tranexamic acid (3%), Resveratrol (1%), Ferulic acid (0.5%), Glabridin (0.15%), Vitamin C Glucoside (5%), Raspberry Ketone Glucoside (2%), Phenylethyl Resorcinol (0.5%), Vitamin E (1%), Hydroxytyrosol (1%), Methoxy Water-Soluble Ferulic Acid Potassium (0.5%), Cinnamon Acid (0.5%), Cinnamic Acid Derivative (3%)
Application method:
Each emulsion applied twice daily for 4 weeks
Application quantity: 2.00±0.05 mg/cm² per test site
Area of application: 7.5 cm² per test site
Total application amount: 15±0.3 mg per test site

Comparator(s):
Positive control: 7% Ascorbic Acid (Vitamin C) emulsion
Negative control: Base emulsion (placebo vehicle)
Blank control: Untreated pigmentation site

Randomisation will be conducted by an independent statistician using an online statistical tool (StatBox: Online Statistical Computing System, Xue Yuqiang & Chen Fangyao. Available at: http://www.cnstat.org/statbox/).
The statistician will generate the randomisation schedule to determine the allocation of test samples, positive control, negative control, and blank control at each pigmentation site.
The randomisation list will be sealed in an envelope, and no allocation information will be disclosed to the investigators, outcome assessors, or data analysts.
Both the assessors and data analysts will remain blinded throughout the study.

Intervention Type
Other

Primary outcome(s)
1. ITA° value (skin color measurement by spectrophotometer) at Day 8 (baseline after pigmentation), Day 15, Day 22, Day 29, and Day 36
2. MI (melanin index measured by Mexameter probe) at Day 8 (baseline after pigmentation), Day

15, Day 22, Day 29, and Day 36
3. Visual skin color assessment (by dermatologist) at Day 8 (baseline after pigmentation), Day 15, Day 22, Day 29, and Day 36

Key secondary outcome(s))
Monitoring and reporting of adverse events such as redness, itching, irritation, or allergic reactions related to the intervention measured using patient records throughout with a summary at Day 36

Completion date
06/12/2025

Eligibility

Key inclusion criteria
1. Healthy male or female participants aged 18 to 60 years
2. Skin ITA° value between 20° and 41°
3. No history of allergic reactions to cosmetics or other topical products
4. No history of photosensitivity disorders or related conditions
5. No pigmentation, scars, or moles at the test site on the back
6. Able to understand the study protocol and provide written informed 7consent to participate in the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Pregnant or breastfeeding women, or those planning pregnancy
2. History of skin diseases such as psoriasis, eczema, atopic dermatitis, or severe acne
3. Recent use (within 1 month) of corticosteroids or skin-lightening products (e.g., hydroquinone)
4. Participation in another clinical trial within the last 2 months
5. Family history of skin cancer or immunosuppression (e.g., HIV positive, organ transplant recipients)
6. Recent (within 8 weeks) exposure to tanning or excessive sun exposure
7. Participants with a history of allergic reactions to cosmetics or other topical products

8. Participants with pigmentation, inflammation, scars, or moles at the test site
9. Inability to comply with study procedures or unwillingness to sign informed consent

Date of first enrolment
01/11/2025

Date of final enrolment
15/11/2025

Locations

Countries of recruitment
China

Study participating centre
DRC(Guangzhou) Testing Technology Co., Ltd
5th Floor, Building B9, No. 11 Kaiyuan Avenue, Science City, Huangpu District, Guangzhou, Guangdong Province
Guangzhou
China
510000

Sponsor information

Organisation
Shenzhen Hujia Technology Co., Ltd.

Funder(s)

Funder type
Industry

Funder Name
Shenzhen Hujia Technology Co., Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
The individual participant data (IPD) will be stored securely and only accessible to authorized personnel within the research team.

The anonymized IPD may be shared with other researchers or institutions for further scientific analysis, subject to ethical review and approval.
Data will not be shared with external parties without prior approval from the sponsor and ethical committee.
IPD will be available upon reasonable request for the purpose of advancing scientific knowledge and improving cosmetic products.
Any data shared will adhere to strict confidentiality agreements and data protection laws, ensuring that participant identities remain anonymous.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	25/08/2025	30/10/2025	No	Yes
Protocol file	in Chinese version 2.0	26/08/2025	30/10/2025	No	No