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Efficacy and safety of skin care approach in the treatment of keratosis pilaris

Submission date
30/03/2025

Recruitment status
No longer recruiting

Registration date
06/04/2025

Overall study status
Ongoing

Last Edited
02/04/2025

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
ackground and study aims
Keratosis pilaris is a chronic skin condition that causes small, rough bumps on the skin. This study aims to test different treatments to see how effective they are in improving this condition.

Who can participate?
Men and women aged 18 to 55 who meet the study's criteria can participate.

What does the study involve?
Participants will be divided into two groups, both receiving topical treatments. The effects will be measured using non-invasive skin tests and questionnaires. Participants will get free treatment for keratosis pilaris. Some may experience mild itching and redness during treatment.

What are the possible benefits and risks of participating?
Participants may benefit from free treatment and potential improvement in their skin condition. Risks include mild itching and redness.

Where is the study run from?
The study is conducted by the Cosmetic Research Center of Beijing Technology and Business University.

When is the study starting and how long is it expected to run for?
April 2024 to September 2025.

Who is funding the study?
The study is funded by Shandong Huawutang Biotechnology Co., Ltd. (China)

Who is the main contact?
The main contact is Professor Meng Hong, Deputy Dean of the International School of Cosmetics at Beijing Technology and Business University. Her email is menghong2000@163.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Efficacy and safety of skin care approach in the treatment of keratosis pilaris: a randomized controlled clinical trial study protocol

Study objectives
A scheme combining body scrub and moisturizing milk has a better effect more than tretinoin in the treatment of keratosis pilaris.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/04/2024, Ethics Committee of Scientific Research of Beijing Technology and Business University (No.11 Fucheng Road, Haidian District, Beijing, 102488, China; +86 15652701818; fantasyee8991@163.com), ref: 2024131

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Home, Laboratory, School, University/medical school/dental school, Workplace

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Keratosis pilaris

Interventions
In this experiment, the randomization method of drawing lots was employed. After all patients were numbered, group numbers were randomly drawn to assign them to different groups for therapeutic research.

The treatment group underwent a comprehensive skin care intervention. Specifically, the upper arms were massaged with moderate pressure. Each arm was then treated with an almond acid scrub for 20-30 seconds, followed by thorough rinsing. Subsequently, a ceramide-based compound body lotion was applied. After rinsing and drying the body, a matching body lotion was applied to the same upper arm, with at least one pump used per arm and massaged thoroughly until fully absorbed.

The control group was treated with 0.1% tretinoin cream. First, the local skin was cleaned using a gentle soap and then gently patted dry. A waiting period of 20-30 minutes was observed to ensure the skin was completely dry. After washing hands, gloves or finger cots were worn to prevent direct contact between the medication and the skin of the hands. An appropriate amount of cream (depending on the size of the affected area) was taken with the fingertip or a cotton swab and applied from the center of the affected area, spreading outward in a clockwise or counterclockwise circular motion. The application site was gently massaged to facilitate full absorption of the medication until the cream completely disappeared.

Intervention Type
Other

Primary outcome measure
The number of follicular papules was recorded by dermatoscope, and the improvement index of follicular papules was calculated at baseline, 7,14,21,and 28 day.

Secondary outcome measures
The skin roughness (SEr), smoothness (SEsm), and scaling index (SEsc) were measured using the skin microscope Visioscan® VC98 at baseline, 7,14,21,and 28 day.

Overall study start date
01/04/2024

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Chinese participants aged 18 to 55 years, who meet the diagnostic criteria for keratosis pilaris.
2. Willing to undergo treatment and complete the course, attend follow-up visits on schedule for photography, and sign an informed consent form.

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
72

Key exclusion criteria
1. Patients with severe organic diseases of important organs such as cardiovascular and cerebrovascular diseases, diabetes, liver and kidney diseases, bleeding disorders, and severe primary hematologic diseases, as well as patients with mental illness.
2. Patients allergic to mandelic acid or other test drugs.
3. Patients with active viral diseases such as herpes simplex or warts at the treatment site, or those who have undergone cryotherapy, radiotherapy, phototherapy, or surgery in the past six months.
4. Patients who have taken oral corticosteroids within the past three months.
5. Patients with immunodeficiency diseases or a history of keloid formation.
6. Patients who are currently participating in or have participated in other clinical studies /treatments within the past three months.
7. Women who are planning to conceive, pregnant, or breastfeeding.
8. Patients whose medical history, physical examination, and laboratory tests can rule out keratosis pilaris secondary to other diseases.

Date of first enrolment
15/04/2024

Date of final enrolment
15/04/2025

Locations

Countries of recruitment
China

Study participating centre
Beijing Technology and Business University
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Sponsor information

Organisation
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Sponsor type
University/education

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Funder(s)

Funder type
Industry

Funder Name
Shandong Huawutang Biotechnology Co., Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request
Dr. Meng, menghong2000@163.com

IPD sharing plan summary
Available on request