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An 8-week study to investigate the benefits of a blue LED facial mask device on acne

Submission date
09/03/2026

Recruitment status
Not yet recruiting

Registration date
09/03/2026

Overall study status
Ongoing

Last Edited
09/03/2026

Condition category
Skin and Connective Tissue Diseases

[X] 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
The purpose of this study is to investigate the effect of a facial device. There will be approximately 30 other volunteers taking part in this study.

Who can participate?
Healthy volunteers aged 14 - 75 years

What does the study involve?
It is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to sign a consent form. You would then still be free to stop at any time and without giving a reason. This will not affect whether we approach you for future studies.
The first visit will be to assess your suitability and give you an opportunity to understand the purpose of the study and to ask study personnel questions. If you consent to the study, your first visit will last around 2 hours. You will then return after 2 weeks, 4 weeks and 8 weeks; these visits will last around 1 hour 30 minutes.
If you are suitable and agree to take part in the study, you will be asked to agree to the following:
Week 0:
1. You will be provided this information sheet to read through to understand the purpose of the study and given time to ask questions regarding this study and any procedures involved.
2. Have the details of your medical history and any medication reviewed and updated by study personnel.
3. Have the nurse assess your skin to ensure you are suitable to take part in the study.
4. Cleanse your whole face using your cleanser at the clinic.
5. Have baseline photographs taken of the front, left side and right side of your face using a photo booth. These photographs will be analysed for surface features such as skin tone, texture and redness.
6. Wait a minimum of 20 minutes in an environmentally controlled room before any measurement procedures take place.
7. Have skin sebum (Sebumeter) measurements on your forehead. These are painless procedures and leave no mark on the skin.
8. You will use the test product for the first time at the clinic, under the supervision of study

personnel.
9. Complete a product questionnaire after your first use of the test product.
10. You will be dispensed the test product for continued use at home. Study personnel will provide you with the usage instructions and a diary card to record use.
Week 2, Week 4 and Week 8:
11. Return to the clinic without makeup on, at the appointment time given to you by study personnel.
12. Have the details of your medical history and any medication reviewed and updated by a study nurse.
13. Cleanse your whole face using your facial cleanser at the clinic.
14. Have repeat photographs taken of the front, left side and right side of your face using a photo booth approximately 10 minutes after you have cleansed.
15. Wait a minimum of 20 minutes in an environmentally controlled room before any measurement procedures take place.
16. Have repeat measurements on your forehead. These are painless procedures and leave no mark on the skin

What are the possible benefits and risks of participating?
There is no benefit to you in taking part in the study. The information gained will be of benefit to future users of these products and similar types of products.
It is unlikely that you will experience any significant problems with the facial products being tested. If you do experience any problems, you can contact Cutest immediately on the number given at the bottom of this information sheet. You may also wish to seek alternative medical advice from your doctor should any problems arise.

Where is the study run from?
Lustre Skin Ltd (UK)

When is the study starting and how long is it expected to run for?
May 2026 to August 2026

Who is funding the study?
Lustre Skin Ltd (UK)

Who is the main contact?
Stewart Long, stewart@cutest.co.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mr Stewart Long

ORCID ID
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Additional identifiers

Study information

Scientific Title
An 8-week study to investigate the benefits of a blue LED facial mask device on acne

Study objectives
The primary objective of the study is to evaluate the efficacy of blue and red light therapy using an LED mask on acne and blemishes when used for 8 weeks.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Single

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Acne

Interventions
Use of an LED mask daily for the study duration. Treatment is daily, every day for 8 weeks. Follow up is for 2 weeks post the final treatment.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Lustre Kin LED mask

Primary outcome(s)
1. Acne lesion count measured using clinical assessment at 0, 4 and 8 weeks

Key secondary outcome(s))
1. Volunteer self perception outcomes of skin appearance and satisfaction measured using questionnaire at 8 weeks

Completion date
30/08/2026

Eligibility

Key inclusion criteria
1. Volunteers who are aged 14-75 years
2. Volunteers who have signed the consent form after the nature of the study has been fully explained
3. Volunteers who are able to provide signed informed consent (> 16 years)
4. Parents who are able to provide signed informed consent for those volunteers <16 years
5. Volunteers who have at least 5 blemishes at the time of consent
6. Volunteers who are willing to cooperate and participate by following study requirements

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
14 years

Upper age limit
75 years

Sex
All

Total final enrolment
37

Key exclusion criteria

1. Pregnant, breastfeeding, or lactating females at the start of the study; those who have given birth in the past 6 weeks or those that planning to become pregnant during the study
2. Volunteers who have taken part in a Health Research Authority or MHRA regulated clinical trial (e.g., at a hospital or phase I unit) within the previous eight weeks
3. Volunteers who have taken part in a study involving the face within the previous 4 weeks
4. Volunteers with a recent history (previous 12 months) of significant skin disease requiring medical intervention, e.g., a dermatology outpatient appointment
5. Volunteers that have a history of facial skin cancer on the test areas
6. Volunteers with photosensitive disorders
7. Volunteers taking medications that can cause photosensitivity
8. Volunteers who have a medical history or seizures triggered by light
9. Volunteers with a recent exposure (previous four weeks) to the sun or sun beds, moderate to pronounced suntan, tattoos, scars or other disfigurement, significant dilated vessels, or other conditions on the test area that, in the opinion of the investigators, might influence the test results
10. Volunteers currently using topically applied prescription medications on/near the test site
11. Volunteers who have had chemical peels, dermabrasion or facial cosmetic surgery within the last 6 months

Date of first enrolment
01/05/2026

Date of final enrolment
31/05/2026

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cutest Systems Ltd
Pendragon House, Caxton Place
Cardiff
Wales
CF23 8XE

Sponsor information

Organisation
Lustre Skin Ltd

Funder(s)

Funder type

Funder Name
Lustre Skin Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available