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Studying how healthy skin reacts to a new LED light device

Submission date	Recruitment status	[_] Prospectively registered
31/03/2026	Recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/04/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/05/2026	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Irradiation monochromators are devices used in the Photobiology Unit (PBU) to measure the reddening effects of light on the skin, a diagnostic test known as phototesting. This information is used by dermatologists to help in identifying skin diseases where they may be increased sensitivity to light and plan for the best possible treatment. However, these light testing devices are expensive and testing can take a long time.
We have developed a new phototest device, which we hope will be quicker and less expensive. We need to test this device and gather ‘normal’ data from healthy volunteers so that we can work out the doses of light to be used when we go on to use this in people who may have altered light sensitivity.

Who can participate?
Adult males and females, aged 18 years and over, who are capable of giving informed consent and who can understand and comply with the protocol requirements and timetables, instructions and protocol-stated restrictions.

What does the study involve?
At your first visit, the study will be fully explained to you. If, after any questions you have are satisfactorily answered, you are happy to take part and if the study is appropriate for you, you will be asked to sign a consent form. You will then be asked questions about your sensitivity to sunlight, whether you are taking any prescribed or over-the-counter medications or supplements or using illicit or recreational drugs. You will also be asked whether you are using any skin products on your lower back, including tanning products, or whether you have been using sunbeds or have had a recent sunburn or tan on your back. There will also be a limited physical examination of the skin on your back to make sure it is clear for testing. Photographs of the exposed areas of skin may be taken at visits 2,3,4 and/or 5. The photographs will be taken in a manner that will not identify you. This visit will last up to 30 minutes.
At your second visit, we will expose areas of skin on your back to varying quantities of ultraviolet-B, ultraviolet-A and visible light. These exposures will be painless. This is very similar to procedures we undertake routinely for patients in our clinics. Each exposure will last from a few minutes up to 30 minutes. The skin on your back will then be assessed for up to 30 minutes. We may also use a device called a reflectance spectrometer. This is held against the skin and a small

flash of light is used to assess skin colour. It is like a photograph and is painless. This visit will last up to three and a half hours. At the end of the visit you will be free to leave the hospital and we will ask you to return the following day (Visit 3).
At your third visit, we will assess the exposure areas by eye and may also take more measurements with the reflectance spectrometer. We will then expose the skin on your back a further time to light of different quantities. As with the day before, each exposure will last from a few minutes up to 30 minutes and the skin on your back will be assessed for up to 30 minutes. On Visit 3, we will inform you if you require more light exposure on Visit 4. This visit will last up to three and a half hours. At the end of Visit 3 you will be free to leave the hospital and we will ask you to return the following day (Visit 4).
At your fourth visit, we will again visually assess the exposure areas and may take more measurements with the reflectance spectrometer. For most, this will be the end of the study and the fourth visit will last around 15 minutes. Uncommonly, we may need to expose the skin on your back to further amounts of light. This will happen if there was no response to the Visit 2 light exposure when we assess you at Visit 3. Each exposure will last from a few minutes up to 30 minutes and the skin on your back will be assessed for up to 30 minutes. If light exposure is required, this visit will last up to two and a half hours. At the end of Visit 4 you will be free to leave the hospital and, if you have received further light exposure, we will ask you to return the following day (Visit 5).
If a fifth visit is required, we will visually assess the exposure areas and may take more measurements with the reflectance spectrometer. There will be no further light exposure and this visit will last around 15 minutes.

What are the possible benefits and risks of participating?
The study will not be of direct benefit to you but may be of benefit to individuals who are sensitive to ultraviolet and visible light. If successful, this study could lead to the routine clinical use of this new phototest device. The main advantages would therefore be less time for patient testing, which would be more comfortable for the patient and more efficient for the NHS.
We do not anticipate any problems, however, there may, as with any research project, be risks of participating that we have not foreseen.
Your health and safety are the most important considerations to the doctors performing this study. The research team will take responsibility for your clinical care during the study. They will halt your participation at any time if they feel that continued participation would be detrimental to you in any way.
There are certain things you should consider about the procedure in the study which may affect your willingness to participate.
The Photobiology Unit has carried out routine phototesting for 50 years as part of patient investigations. In the current study we are using a different type of light testing device, which is LED-based. Phototesting involves exposing the skin on your back to different wavelengths and doses of light. This will result in small areas of redness on your back. In most cases phototesting is not painful and the redness will go away within a few days. However, in some cases the redness may stay for weeks or even months. Sometimes the skin may become brown (pigmented /tanned) and this may, in rare circumstances, last for weeks or months. The risks of any delayed, long-term effects are expected to be negligible with such short-term exposure

Where is the study run from?
The Photobiology Unit at Ninewells Hospital in Dundee, Scotland (UK)

When is the study starting and how long is it expected to run for?
The study begins in March 2025 and expected to run until December 2026.

Who is funding the study?
British Skin Foundation (UK)

Who is the main contact?
1. Susan Yule, susan.yule@nhs.scot
2. Prof. Sally Ibbotson, s.h.ibbotson@dundee.ac.uk

Contact information

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
335176

Central Portfolio Management System (CPMS)
65572

Public registry ID Number
researchregistry9666

Study information

Scientific Title
Determining reference ranges for a novel light emitting diode (LED) phototest device

Acronym
LED-REF

Study objectives
To establish a normal range of erythemal sensitivity in healthy volunteers for the developed LED-based phototest device. To compare erythemal sensitivity between the developed LED-based phototest device and an irradiation monochromator, which is the current diagnostic equipment used in routine practice.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/12/2024, Health and Social Care Research Ethics Committee A (HSC REC A) (Lissue Industrial Estate West 5 Rathdown Walk, Lisburn, BT28 2RF, United Kingdom; +44 (0)28 95 361400; reca@hscni.net), ref: 24/NI/0138

Primary study design
Interventional

Allocation
N/A: single arm study

Masking

Open (masking not used)

Control
Dose comparison

Assignment
Single

Purpose
Device feasibility, Diagnostic

Study type(s)

Health condition(s) or problem(s) studied
Erythema reaction of non-photosensitive individuals to various wavelengths of LED light

Interventions
The study will consist of the following interventions and assessments:

Visit 1
Screening/inclusion & exclusion/informed consent

Visit 2 (Day 0) Up to 30 days from Visit 1
1. Non-invasive reflectance measurement of the back for an objective measurement of skin colour
2. Back irradiated with the LED-based phototest device at various wavelengths and doses
3. Back irradiated with an irradiation monochromator, which is our routine clinical phototest equipment, at various wavelengths and doses
4. Visual observation of the test sites for urticaria, for up to 30 minutes

Visit 3 (Day 1) +1 day from Day 0
1. Visual observation of MED on skin around 24 hours post initial exposure. Recording of skin response.
2. Further irradiation of the back with the LED-based phototest device. Doses delivered will be between the MED and the highest No-Response Dose (NRD)
3. Further irradiation of the back with the irradiation monochromator. Doses delivered will be between the MED and the highest No-Response Dose (NRD)
4. Non-invasive reflectance measurement may be taken to assess any non-visual changes
5. If no MED following Day 0 irradiation then higher doses may be delivered

Visit 4 +1 (Day 2) day from Day 1
1. Visual observation of MED on skin @ around 24 hours post Day 1 exposure. Recording of skin response
2. Non-invasive reflectance measurement may be taken to assess any non-visual changes
3. If no MED following Day 1 irradiation, then further irradiation of the back may occur with the LED-based phototest device and/or irradiation monochromator at higher doses than delivered on Day 1

Visit 5 (Day 3), if required, +1 day from Day 2
1. Visual observation of MED on skin @ around 24 hours post Day 2 exposure. Recording of skin response
2. Non-invasive reflectance measurement may be taken to assess any non-visual changes

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
LED-based phototest device

Primary outcome(s)
1. Erythema from LED-based phototest device measured using a semi-quantitative visual scoring of erythema or reflectance measurements of skin colour if no visual erythema observed at 24±2 hours after exposure

Key secondary outcome(s)
1. Erythema from irradiation monochromator measured using a semi-quantitative visual scoring of erythema or reflectance measurements of skin colour if no visual erythema observed at 24±2 hours after exposure

Completion date
21/12/2026

Eligibility

Key inclusion criteria
1. Healthy persons with no clinically significant abnormality identified by participant reported medical history, in particular no evidence of abnormal photosensitivity
2. Adult males and females, >18 years only
3. Capable of giving informed consent
4. Able to understand and comply with protocol requirements and timetables, instructions and protocol-stated restrictions

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
999 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Any photosensitising medication or supplement (systemic or topically applied to the test area) within 14 days prior to testing
2. Insufficient clear, untanned, unaffected skin on the back to allow minimal erythema dose (MED) testing
3. Participation in a clinical study involving administration of an investigational drug (new chemical entity/non-licensed drug) or in a clinical study involving administration of a marketed drug within the past 3 months
4. Known to have abnormal photosensitivity
5. Pregnant or breastfeeding
6. Use of self-tanning products on the back (test area) in the preceding 2 weeks
7. Sunbed exposure or natural sunlight-induced sunburn or tan on the back (test area) acquired within the four weeks prior to recruitment
8. Immunosuppression due to medications (such as organ transplant recipient) or disease (including HIV or haematological malignancy)
9. History of skin cancer, not including basal cell carcinoma (BCC)
10. History of malignancy not curatively treated at least 5 years before screening visit, with exception of BCC or cervical carcinoma in situ, which may have been curatively treated within 1 year
11. History of current use of illegal or ‘recreational’ drugs
12. Any condition which, in the opinion of the investigator, might put the subject at risk by participating in this study

Date of first enrolment
17/03/2026

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Ninewells Hospital
Ninewells Avenue
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Sponsor information

Organisation
University of Dundee

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type

Funder Name
British Skin Foundation

Alternative Name(s)
The British Skin Foundation, bsfcharity, BSF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	19/08/2024	12/05/2026	No	No