

An investigation into the barrier function and barrier forming proteins of the skin in polymorphic light eruption

Submission date 29/10/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/10/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/01/2021	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Polymorphic light eruption (PLE) is the most common allergy to the sun. It affects 18% of the population of northern Europe. A itchy, but none scarring, skin rash occurs around 4-6 hours after exposure to the sun. Very little is known about what causes PLE. It has been suggested that an allergen formed in or on the skin upon sun exposure is responsible for the rash, but this photoallergen has not yet been identified. Other researchers believe that PLE patients are less likely to suppress the effects of the sun on the skin compared to healthy people. One of the skin's most important roles is to form a barrier between the inside of the body and the environment outside. This barrier is made up of special proteins, which act to prevent water being lost from the skin as well as pathogens entering to the body. Recent work in our laboratory has shown that specific barrier forming proteins of the skin are altered in PLE. A damaged barrier may be more prone to movement of photoallergens through the skin leading to the cause of PLE symptoms. The aim of this study is to investigate the function of the skin barrier in PLE patients before and after exposure to ultraviolet light, and to test the effect of barrier reinforcing molecules on the skin barrier.

Who can participate?

Healthy volunteers or PLE patients who are white caucasians and between 30-60 years old

What does the study involve?

Participants have their sunburn threshold tested on their upper buttock skin. Small skin biopsies are taken from areas exposed to UV light and from unexposed skin for laboratory analysis of skin barrier function. Skin water loss is measured from UV-exposed and unexposed skin.

What are the possible benefits and risks of participating?

Participants do not benefit directly from taking part in this study, but the information gathered will lead to a further understanding of the cause of PLE.

Where is the study run from?

This study is being performed in the Photobiology Unit, Salford Royal NHS Foundation Trust and the dermatology research laboratories at the University of Manchester (UK)

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

February 2014 to August 2015

Who is funding the study?

British Skin Foundation (UK)

Who is the main contact?

Dr Mark Farrar

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Contact information

Type(s)

Scientific

Contact name

Dr Mark Farrar

Contact details

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Additional identifiers

Protocol serial number

17590

Study information

Scientific Title

A non-randomised trial investigating the barrier function and barrier forming proteins of the skin in polymorphic light eruption

Study objectives

1. The barrier function of the skin is compromised in polymorphic light eruption
2. Abnormal tight junction protein expression is related to skin barrier defects in polymorphic light eruption
3. The barrier can be improved using food-derived molecules

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North West - Greater Manchester West; 13/01/2014, ref. 13/NW/0797

Study design

Non-randomised; Interventional and Observational; Design type: Not specified, Clinical Laboratory Study

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Topic: Dermatology; Subtopic: Skin (all Subtopics); Disease: Dermatology

Interventions

Measurements of water loss of the skin will be taken from sun protected buttock skin. To assess sunburn threshold, standard minimal erythema dose (MED) testing will be performed where another area of photoprotected buttock skin will be exposed to twelve controlled doses of UV with each exposure site being approximately 1cm in diameter. Twenty-four hours later, water loss measurements will be repeated and erythema (redness) assessed.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Barrier forming protein function. Timepoint(s): 24h

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/08/2015

Eligibility**Key inclusion criteria**

1. Healthy volunteers or PLE patients that have reached diagnostic criteria for PLE (through patient questionnaire and clinical diagnosis)
2. White Caucasians of photoreactive skin type I-III
3. Female (not pregnant) or male 30-60 years
4. Volunteers giving written informed consent

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. People who smoke
2. People with other conditions exacerbated by light
3. People taking photoactive medication
4. People unable to complete the visit requirements of the protocol
5. Inability to comply with all requirements of the protocol
6. History of sunbathing or artificial UV exposure in the previous 3 months
7. History of skin cancer

Date of first enrolment

24/02/2014

Date of final enrolment

31/08/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Hope Hospital

Salford

United Kingdom

M6 8HD

Sponsor information

Organisation

University of Manchester (UK)

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Charity

Funder Name

British Skin Foundation; Grant Codes: S1004

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes