ISRCTN44480072 https://doi.org/10.1186/ISRCTN44480072

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

Registration date
29/10/2014

Overall study status
Completed

Last Edited
28/01/2021

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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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-
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Details of who to contact can be found at: www.citizenscientist.org.uk/research-opportunities/healthy-volunteers/skin-barrier-and-ultraviolet-light-exposure/

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
24/02/2014

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50; Description: To account for drop out rate study team anticipate recruitment between 40-60 participants.

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
England

United Kingdom

Study participating centre
Hope Hospital
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
British Skin Foundation; Grant Codes: S1004

Alternative Name(s)
BSF

Funding Body Type
Private sector organisation

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

Location

United Kingdom

Results and Publications

Publication and dissemination plan

2016 non-peer-reviewed thesis in https://ethos.bl.uk/OrderDetails.do?uin=uk.bl.ethos.684803 (added 25/01/2021)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No