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Lipid mediators of ultraviolet radiation (UVR) induced skin inflammation

Submission date	Recruitment status	[_] Prospectively registered
20/10/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/10/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/01/2017	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
When human skin is exposed to sunlight it develops an inflammatory response known as sunburn. This is a major factor for skin damage, premature skin ageing and the development of cancer. We have discovered that very potent fat (lipid) molecules called eicosanoids are produced by the body during the early stages of sunburn. However, there is a lack of studies on how these molecules contribute to resolving skin inflammation. In this study we want to investigate the network of lipids that are responsible for resolving skin inflammation. We wish to study (a) the timing for the production of specific lipids and how this may differ in people who tend to sunburn compared to those who tend to tan, (b) the effect of nutrients contained in fish oils that have been shown to possess sun-protective effects, and to understand (c) how sunlight and nutrients in the diet may affect the manufacture of these lipids and (d) the contribution to this made by different types of skin cells. Understanding how sunburn is resolved will reveal biological markers (biomarkers) related to skin inflammation and can help with the discovery of new treatments.

Who can participate?
Healthy white Caucasian male and female individuals aged between 18 and 60 years.

What does the study involve?
Exposure of the skin on the upper buttock to ultraviolet light (UV), measurements of skin redness, and skin sampling (skin biopsies or skin blisters) from unexposed and UV-exposed areas of the upper buttock. Participants will also take oral omega-3 fatty acid supplements for 3 months.

What are the possible benefits and risks of participating?
Understanding how sunburn is resolved will reveal biomarkers related to skin inflammation and can help with the discovery of new treatments. We do not expect there to be any disadvantage or adverse effect from taking part. You may experience some redness of the skin after the UV exposures. Some discomfort will be felt at the time of skin sampling and in the days following the procedures, which may include redness, irritation and pain at the site. There is also a small risk of infection and bleeding with biopsies. A small permanent scar will be left on your skin at each biopsy site.

Where is the study run from?
The Photobiology Unit at Salford Royal NHS Hospital (Salford, UK).

When is the study starting and how long is it expected to run for?
October 2011 to October 2014.

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Miss Suzanne Pilkington

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10920

Study information

Scientific Title
Identifying the network of lipid mediators responsible for maintenance and resolution of ultraviolet radiation-induced skin inflammation

Study objectives

The aim of this study is to investigate the network of lipids that are responsible for resolving skin inflammation. A study in healthy adult volunteers and patients with abnormal responses to sunlight i.e. photosensitivity, will assess
1. The timing for the production of specific lipids and how this may differ in people who tend to sunburn compared to those who tend to tan
2. How this may differ between healthy people and those showing abnormal clinical responses to sunlight
3. The effect of nutrients contained in fish oils that have been shown to possess sun-protective effects.
Understanding how sunburn is resolved, will increase our understanding of skin inflammation and can facilitate the discovery of new therapeutic agents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West-GM North, 22/08/2011, ref: 11/NW/0567

Study design
Non-randomised, interventional and observational, clinical laboratory study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Topic: Skin; Subtopic: Skin (all Subtopics); Disease: Dermatology

Interventions
Omega-3 PUFA (Incromega EPA500TG - fish oil supplements rich in omega-3 PUFAs) administered at 4g daily for 3 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Concentration of bioactive lipids in skin samples following UVR exposure measured at 3 months

Secondary outcome measures
1. Number of infiltrating inflammatory/immune cells during and until resolution of UVR induced inflammation measured at 3 months
2. The expression of key bioactive lipid metabolising enzymes and receptors in human skin measured at 3 months

Overall study start date
01/10/2011

Completion date
01/10/2014

Eligibility

Key inclusion criteria
1. Healthy, human volunteers and patients with defined photosensitivity conditions.
2. Aged 18 - 60 years
3. Sun reactive skin type I - IV (white Caucasian)
4. Both male & female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 125; UK Sample Size: 125

Key exclusion criteria
1. History of skin cancer
2. Taking photoactive or anti-inflammatory medication
3. Sunbathing, sunbed use or phototherapy in the past 3 months
4. Taking nutritional supplements containing polyunsaturated fatty acids (PUFA)
5. Consuming more than 2 portions of oily fish per week
6. Pregnancy
7. Unable to eat fish or gelatine

Date of first enrolment
01/10/2011

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Photobiology Unit, Dermatological Sciences
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
University of Manchester

Sponsor details
Faculty of Medical and Human Sciences Research Office
3.53 Simon Building
Manchester
England
United Kingdom
M13 9PT

Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) ref: 094028/B/10/Z

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration