

# Lipid mediators of ultraviolet radiation (UVR) induced skin inflammation

<b>Submission date</b> 20/10/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/10/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/01/2017	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?

Dr Suzanne Pilkington

Suzanne.pilkington@manchester.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Miss Suzanne Pilkington

### Contact details

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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