

# Fish oil in nickel sensitivity: an immunonutritional approach to the prevention of skin cancer

<b>Submission date</b> 26/02/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/03/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/04/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.manchester.ac.uk/medicine/dermatological>

## Contact information

### Type(s)

Scientific

### Contact name

Prof Lesley Elizabeth Rhodes

### Contact details

Photobiology Unit  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

NCT01032343

**Secondary identifying numbers**

N/A

## **Study information**

**Scientific Title**

Oral omega-3 polyunsaturated fatty acid (n-3 PUFA) supplementation in ultraviolet radiation (UVR) induced cutaneous immunosuppression: a single site, double-blind, randomised, placebo controlled nutritional study

**Study objectives**

Exposure to ultraviolet radiation (UVR) is a major cause of skin cancer development and acts to initiate cancer as well as promoting tumour development through photo-immunosuppression. Protection against photo-immunosuppression of contact hypersensitivity (CHS) in experimental models has been shown to correlate with protection against photocarcinogenesis.

Experimental models show that photo-immunosuppression, and consequently photocarcinogenesis, is reduced by dietary intervention with omega-3 polyunsaturated fatty acid (n-3 PUFA). However, this has not been directly explored in humans. Positive results from this study would lead to further research examining the influence of n-3 PUFA on skin cancer occurrence.

We hypothesise that oral n-3 PUFA supplements will protect against UVR induced cutaneous immunosuppression in humans.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

North Manchester Research Ethics Committee gave approval on the 13th June 2008 (ref: 08 /H1006/30)

**Study design**

Single centre, double-blind, randomised, placebo controlled nutritional study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

## **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**

Skin cancer prevention

## **Interventions**

Active: fish oil supplements rich in n-3 PUFAs (Incromega E7010 SR, Croda, UK); 5 x 1 g capsules to be taken with breakfast

Control (placebo): medium chain triglyceride oil (GTCC, Croda, UK); 5 x 1 g capsules to be taken with breakfast

For each volunteer, the duration of nutritional supplementation is 12 weeks; follow-up is 2 weeks.

## **Intervention Type**

Supplement

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Omega-3 polyunsaturated fatty acid (n-3 PUFA) supplementation

## **Primary outcome measure**

To examine the protective effect of n-3 PUFA on:

1. UVR-induced suppression of clinical CHS responses using the International Contact Dermatitis Research Group (ICDRG) grading scale: No reaction (-) to extreme positive (+++)
2. UVR-induced modulation of immune cells (epidermal Langerhans cells) using immunohistochemistry of epidermal sheets

Assessed simultaneously at 13 weeks.

## **Secondary outcome measures**

Levels of immunoregulatory mediators in the skin using mass spectrometry analysis and Luminex analysis of cytokine expression in suction blister fluid. Assessed simultaneously at 13 weeks.

## **Overall study start date**

02/03/2009

## **Completion date**

31/08/2010

## **Eligibility**

### **Key inclusion criteria**

1. Female
2. Aged 18 - 60 years

3. Sun reactive skin type 1 or 2
4. Reporting allergy to jewellery with nickel content

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

64

**Key exclusion criteria**

1. History of atopy
2. History of skin cancer
3. History of a photosensitivity disorder
4. Sunbathing in the past 3 months
5. Pregnancy
6. History of cardiac disease
7. Taking of photoactive medication
8. Not able to eat fish or gelatin
9. Taking fish oil supplements prior to the study
10. Consuming more than 3 meals containing oily fish per week

**Date of first enrolment**

02/03/2009

**Date of final enrolment**

31/08/2010

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Photobiology Unit**

Manchester

United Kingdom

M6 8HD

# Sponsor information

## Organisation

University of Manchester (UK)

## Sponsor details

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## Sponsor type

University/education

## Website

<http://www.manchester.ac.uk/>

## ROR

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

# Funder(s)

## Funder type

Charity

## Funder Name

Association for International Cancer Research (AICR) (UK) (ref: 08-0131)

## Alternative Name(s)

AICR

## Funding Body Type

Private sector organisation

## Funding Body Subtype

International organizations

## Location

United Kingdom

## Results and Publications

### Publication and dissemination plan

Planned publication in a nutrition journal.

### Intention to publish date

31/03/2013

### 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?
<a href="#">Results article</a>	results	01/03/2013		Yes	No
<a href="#">Results article</a>	results	01/03/2014		Yes	No