

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01032343

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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

United Kingdom

England

Study participating centre**Photobiology Unit**

Manchester

United Kingdom

M6 8HD

Sponsor information

Organisation

University of Manchester (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

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?
Results article	results	01/03/2013		Yes	No
Results article	results	01/03/2014		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes