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

Submission date	Recruitment status	[_] Prospectively registered
26/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/03/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/04/2018	Cancer	

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

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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)

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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?
Results article	results	01/03/2013		Yes	No
Results article	results	01/03/2014		Yes	No