

The effect of omega-3 in non-alcoholic fatty liver disease

Submission date 19/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/08/2016	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7156

Study information

Scientific Title

The effect of n-3 polyunsaturated fatty acid (PUFA) supplementation in patients with steatosis due to non-alcoholic fatty liver disease

Study objectives

Assess the effects of a 3 month PUFA supplementation versus placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Nottingham Research and Ethics Committee 1, 11/03/2008, ref: 08/H0403/14

Study design

Single centre randomised interventional treatment trial

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

Topic: Metabolic and Endocrine; Subtopic: Metabolic and Endocrine (all Subtopics); Disease: Metabolic & Endocrine (not diabetes)

Interventions

58 patients with biopsy proven steatosis due to non-alcoholic fatty liver disease (NAFLD) will be randomised to 3.5 g n-3 polyunsaturated fatty acid (PUFA) or oleic enriched sunflower oil capsules for 3 months.

Follow-up length: 3 months

Study entry: registration and one or more randomisations

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Fructose, glucose

Primary outcome measure

Hepatic steatosis as determined by magnetic resonance imaging (MRI) spectroscopy pre- and post-intervention

Liver fat stores (MR spectroscopy), measured pre- and post-intervention

Secondary outcome measures

Measured pre- and post-intervention:

1. Liver biochemistry
2. Lipid profile
3. Insulin resistance
4. Blood pressure
5. Abdominal visceral fat
6. Inflammatory cytokine profile

Overall study start date

12/01/2009

Completion date

01/12/2009

Eligibility

Key inclusion criteria

1. Age greater than 18 years, either sex
2. Liver biopsy showing NAFLD

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 58; UK sample size: 58

Key exclusion criteria

1. Excessive alcohol intake - greater than 21 units per week in men and greater than 14 in women
2. A further liver disease diagnosis
3. Poorly controlled diabetes - HbA1c greater than 8.0%

4. Pregnancy
5. Cirrhosis
6. Significant inflammation on liver biopsy - classified as a Brunt moderate or severe
7. Life expectancy of less than 2 years
8. Contraindications to MR scanning - pacemaker or metallic foreign body
9. Changes in the dose or initiation of lipid altering medication within the preceeding three months, such as statins, fibrates or systemic steroids
10. Use of n-3 PUFA supplements within the prior 4 months, an adequate washout period

Date of first enrolment

12/01/2009

Date of final enrolment

01/12/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Nottingham University Hospital

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

University of Nottingham (UK)

Sponsor details

Wolfson Digestive Diseases Centre

South Block, C-Floor

Queens Medical Centre

Derby Road

Nottingham

England

United Kingdom

NG7 2UH

Sponsor type

University/education

Website

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

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

Charity

Funder Name

Association of Medical Research Charities (AMRC) - CORE

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