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

Submission date	Recruitment status	[ ] Prospectively registered
19/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/08/2016	Digestive System	[ ] 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