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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Hepatic steatosis as determined by magnetic resonance imaging (MRI) spectroscopy pre- and post-intervention
Liver fat stores (MR spectroscopy), measured pre- and post-intervention

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

United Kingdom

England

Study participating centre
Nottingham University Hospital
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

Funder Name
Association of Medical Research Charities (AMRC) - CORE

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes