

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

<b>Submission date</b> 19/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 24/08/2016	<b>Condition category</b> 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

**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