ISRCTN19987575 https://doi.org/10.1186/ISRCTN19987575

The Influence of n-3 Fatty acid Supplementation on Vascular and Cognitive Function in Healthy Young Adults; a Randomized Controlled Trial

Submission date
27/01/2005

Recruitment status
No longer recruiting

Registration date
05/05/2005

Overall study status
Completed

Last Edited
03/07/2013

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Atul Singhal

Contact details
Institute of Child Health
London
United Kingdom
WC1N 1EH
+44 (0)2079052389
a.singhal@ich.ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N3RCT07

Study information

Scientific Title

Acronym
N3RCT

Study objectives
Primary:
Cardiovascular:
n-3 PUFA supplementation improves vascular function (flow-mediated endothelial dependent dilation) in healthy young adults.

Cognitive:
n-3 PUFA supplementation improves cognitive function in healthy young adults.

Secondary:
Cardiovascular:
n-3 PUFA supplementation improves other cardiovascular risk-factors in healthy young adults (vascular, biochemical and haematological).

Cognitive:
n-3 PUFA supplementation improves mood in healthy young adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
Docosahexaenoic acid v Placebo

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Cardiovascular:
Flow mediated endothelial dependent dilatation of the brachial artery, arterial distensibility and pulse wave velocity.

Cognitive:
CANTAB (CAmbridge Neuropsychological Test Automated Battery).

Secondary outcome measures
Cardiovascular:
Plasma and red cell DHA and EPA levels and biochemical and haematolgical risk factors for CVD including such as fasting insulin, glucose, 32-33 split proinsulin, and leptin concentration and lipid profile including lipoprotein particle size will be determined. Hematological risk factors for CVD will include FBC, fibrinogen, factors VII and VIII, von Willebrand factor, soluble thrombomodulin and tissue plasminogen activator concentrations and inflammatory markers such as IL-6, IL-8 and CRP. Evidence of endothelial cell activation will be sought by the measurement of intra cellular adhesion molecule¿1 (ICAM-1), vascular cell adhesion molecule¿1 (VCAM-1), E-selectin, P-selectin IL-6 and other cell adhesion factors.

Cognitive:
Wechsler Abbreviated Scale of Intelligence (WASI; 29); inspection time, and a self-administered measure of mood (5 minutes) using visual analogue scales.

Overall study start date
01/11/2004

Completion date
31/05/2006

Eligibility

Key inclusion criteria
Healthy volunteers

Participant type(s)
Healthy volunteer

Age group

Adult

Sex
Not Specified

Target number of participants
300

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2004

Date of final enrolment
31/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Child Health
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
Institute of Child Health (UK)

Sponsor details
30 Guilford Street
London
United Kingdom
WC1N 1EH
+44 (0)20 7242 9789
t.austin@ich.ucl.ac.uk

Sponsor type
Government

Website
http://www.ucl.ac.uk/ich/homepage

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Not defined

Funder Name
Part of MRC Programme Grant

Funder Name
Kellogg's Sales & Marketing plc

Funder Name
Martek Biosciences plc

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/07/2013		Yes	No