

The OPAL Study: Older People And n-3 Long-chain polyunsaturated fatty acids

Submission date 27/05/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/07/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/04/2010	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.lshtm.ac.uk/msu/opal/index.html>

Contact information

Type(s)
Scientific

Contact name
Dr Alan Dangour

Contact details
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7958 8133
Alan.Dangour@lshtm.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

OPAL

Study objectives

There is considerable interest in the hypothesis that improving the diet of older people, specifically increasing the dietary intake of n-3 long-chain polyunsaturated fatty acids (n-3 LCPs) may be able to delay the initiation, or slow the progression, of cognitive decline. To date, there has been little attention given to the possible protective role of n-3 LCPs in age-related loss of cognitive or retinal function. OPAL is a double-blind randomised placebo-controlled trial carried out among adults aged 70-79 years in the UK. The intervention arm will receive a daily capsule containing 700 mg n-3 LCP (both decosahexaenoic acid DHA and eicosapentaenoic acid EPA) while the placebo arm will receive a daily capsule containing olive oil. The main outcome variable assessed at 24 months will be cognitive performance and a second major outcome variable will be retinal function. Retinal function tests are included as the retina is a specifically differentiated neural tissue and therefore represents an accessible window into the functioning of the brain. The overall purpose of this public-health research is to help define a simple and effective dietary intervention aimed at maintaining cognitive and retinal function in later life. This is the first trial of its kind aiming to slow the decline of cognitive and retinal function in older people by increasing daily dietary intake of n-3 LCPs. The link between cognitive ability, visual function and quality of life among older people suggests that this novel line of research may have considerable public health importance.

Study hypotheses:

1. For healthy, cognitively normal adults aged 70-79 years of age, daily supplementation with n-3 LCPs (500 mg DHA and 200 mg EPA) will slow the rate, or delay the onset, of cognitive decline.
2. For healthy, cognitively normal adults aged 70-79 years of age, daily supplementation with n-3 LCPs (500 mg DHA and 200 mg EPA) will improve visual function by enhancing rod photoreceptor response to light and visual-cortical integration.

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

Patient information on the various different aspects of the trial can be found on the website at:
<http://www.lshtm.ac.uk/msu/opal/information.html>

Health condition(s) or problem(s) studied

Cognitive and retinal function

Interventions

Daily nutritional supplement of 0.7 g of n-3 long chain polyunsaturated fatty acids (fish oil) versus placebo.

The main outcome variable assessed at 24 months will be cognitive performance and a second major outcome variable will be retinal function (Moorfields Eye Hospital will undertake retinal testing in a sub group).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Change in cognitive function at 24 months determined by the California Verbal Learning Test
2. Change in rod sensitivity over 24 months of intervention as measured by electroretinogram

Secondary outcome measures

1. Cognitive performance as measured by immediate and delayed recall of a short story, tests of prospective memory, timed letter search/cancellation task, verbal fluency, digit span backwards, symbol digit modalities test, simple and choice reaction time, dual-task performance and spatial memory
2. Blood pressure
3. Measure of depression
4. Change in Body Mass Index
5. Compliance determined by counting the number of tablets remaining every 3 months, and by measuring the change in n-3 LCP concentration in buccal epithelial cells over 24 months
6. Number of hospital admissions for cardiovascular events over 24 months
7. Death
8. Colour vision measured by detecting sensitivity to colour contrast which is a good marker of central retinal function
9. Eye health assessed by carrying out a full ophthalmic examination

Overall study start date

01/03/2004

Completion date

31/03/2007

Eligibility

Key inclusion criteria

Healthy volunteers aged between 70-79 years of age, who have no previous history of diabetes or dementia. Participants will be selected from 20 GP practices.

Participant type(s)

Healthy volunteer

Age group

Senior

Sex

Not Specified

Target number of participants

800

Key exclusion criteria

1. Pre-existing type I or type II diabetes at baseline
2. Pre-existing dementia at baseline
3. Reported daily use of fish-oil supplements (in liquid or capsule form) at baseline
4. Mini-mental state examination (MMSE) score <24 at baseline screen

Date of first enrolment

01/03/2004

Date of final enrolment

31/03/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

London School of Hygiene and Tropical Medicine

London

United Kingdom

WC1E 7HT

Sponsor information

Organisation

Medical Research Council (UK)

Sponsor details

Dr Ian Viney
Stephenson House
158-160 North Gower Street
London
United Kingdom
NW1 2ND
+44 (0)20 7670 4625
iv@centre-london.mrc.ac.uk

Sponsor type

Research council

ROR

<https://ror.org/03x94j517>

Funder(s)**Funder type**

Government

Funder Name

UK Food Standards Agency

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?
Protocol article	protocol	31/08/2006		Yes	No
Results article	results	01/06/2010		Yes	No

