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

Submission date 27/05/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 14/07/2004	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 27/04/2010	**Condition category** Eye Diseases	[_] 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

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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
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Sponsor information

Organisation
Medical Research Council (UK)

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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