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Double-masked, randomized, parallel, comparative study of oral supplementation with DecosaHexaenoic Acid (DHA) versus placebo in the prevention of age-related macular degeneration

Submission date 24/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/06/2007	**Overall study status** Completed	
Last Edited 24/02/2016	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NAT 2

Study information

Scientific Title
Double-masked, randomized, parallel, comparative study of oral supplementation with DecosaHexaenoic Acid (DHA) versus placebo in the prevention of age-related macular degeneration

Study objectives
Oral supplementation of DHA is able to delay the occurrence of neovessels in the fellow eye of patients already presenting neovascular age-related macular degeneration in one eye

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee for the Protection of Persons (CPP) Ile de France 5 Paris (formerly Comités de Consultation pour la Protection des Personnes se prêtant à la Recherche Biomédicale [CCPPRB] Paris Saint Antoine), 22/07/2003

Study design
Randomized double-masked placebo-controlled single-centre study on two parallel groups

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Macular degeneration

Interventions
Intervention group:
Oral supplementation with 840 mg of DHA per day (3 capsules per day [2 capsules at midday and 1 capsule in evening]) for 3 years
Control group:
Placebo (olive oil) 3 capsules per day [2 capsules at midday and 1 capsule in evening]) for 3 years

Intervention Type

Supplement

Primary outcome measure
Time to occurrence of choroidal new vessels in the study eye from prospective assessment of fluorescein angiography

Secondary outcome measures
Efficacy (in study eye):
1. Percentage of patients for whom new vessels occur during the study
2. Change from baseline in visual acuity in LogMar units and proportion of patients with a visual acuity decrease from baseline of more than 15 letters at Early Treatment Diabetic Retinopathy Study (ETDRS) assessed at 6 months, Year 1, Year 2 and Year 3
3. Change from baseline in visual function assessed with a multi-focal ElectroRetinoGram (ERG) at Year 3
4. Occurrence and progression of drusen (number, size and area) at 6 months, Year 1, Year 2 and Year 3
5. DHA concentration changes in red blood cell membranes at 6 months and Year 3

Safety:
6. Change in slit lamp examination at 6 months, Year 1, Year 2 and Year 3
7. Intra-ocular pressure change from baseline at 6 months, Year 1, Year 2 and Year 3
8. Change from baseline in profile of plasma lipoproteins at 6 months and Year 3
9. Adverse or unexpected events

Overall study start date
23/12/2003

Completion date
30/11/2008

Eligibility

Key inclusion criteria
1. Male or female outpatients
2. Aged at least 55 years and less than 85 years
3. Having given written informed consent
4. Presenting neovascular age-related macular degeneration in one eye
5. Lesions of age-related maculopathy (confluent and diffuse hard drusen and/or soft drusen with or without pigmentary changes and/or reticular pseudodrusen)
6. Visual acuity of at least +0.4 LogMar (at least 4/10) in the fellow eye (study eye)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Choroidal new vessels in both eyes
2. Wide central area of geographic atrophy encroaching on fovea in the study eye
3. History of other progressive ocular disease, which may complicate the assessment of age-related macular degeneration (severe glaucoma, other severe retinopathy)
4. Opacity precluding evaluation of retina photograph
5. History of serious systemic disease, which may prevent patients long-term participation in the study
6. Patients treated with anticoagulants or predisposed to bleeding or hemorrhage
7. History of an allergic reaction to fluorescein injection or to indocyanin green
8. Known sensitivity to DHA or vehicle
9. Treatment with Maxepa or DHA within the previous 6 months
10. Treatment with vitamin E
11. Any concomitant nutritional supplementation
12. Involvement in the last 30 days in any other investigational drug study
13. Monocular patients (for any reason other than age-related macular degeneration)

Date of first enrolment
23/12/2003

Date of final enrolment
30/11/2008

Locations

Countries of recruitment
France

Study participating centre
Hôpital intercommunal de Créteil
Créteil
France
94000

Sponsor information

Organisation
Laboratoire Chauvin, Bausch & Lomb Inc. (France)

Sponsor details
416
Rue Samuel Morse

CS 99535
Montpellier cedex 2
France
34961

Sponsor type
Industry

ROR
https://ror.org/018qejt38

Funder(s)

Funder type
Industry

Funder Name
Laboratoire Chauvin, Bausch and Lomb group (France)

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	01/07/2015		Yes	No
Results article	results	22/02/2016		Yes	No