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Oral supplementation of omega-3 and omega-6 in dry eye syndrome

Submission date	Recruitment status	[ ] Prospectively registered
23/10/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/11/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/12/2008	Eye Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Study #425

Study information

Scientific Title
A three-month, multicentre, double-masked, randomised, controlled, clinical study to investigate the efficacy of Medilar™ in patients suffering from dry eye syndrome

Study objectives
Oral supplementation of omega-3 and omega-6 can reduce inflammatory markers in conjunctival cells of patients suffering from dry eye syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Italy:
1. Ethics Committee of the San Martino University Hospital (Azienda Ospedaliera Universitaria San Martino) gave approval on the 17th February 2006 (ref: 0016378/06)
2. Ethics Committee of the University Polyclinic (Azienda Policlinico Universitario) gave approval on the 12th January 2006 (ref: E 625/05)

France:
1. Ethics Committee CCPPRB de Bourgogne gave approval on the 29th September 2005 (ref: 2005/20)

Study design
Randomised, double-masked, two-armed, parallel group, placebo-controlled, multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dry eye syndrome

Interventions
Test product - Medilar™:
Oral supplementation with 855 mg of omega-3 and 15 mg of omega-6, vitamins (C,E, B6, B12) and zinc per day (3 capsules per day) for 3 months.

Comparator:
Placebo (medium chain triglycerides), 3 capsules per day for 3 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Omega-3, omega-6 (Medilar™)

Primary outcome measure
Percentage of conjunctival epithelial cells expressing human leukocyte antigen DR-1 (HLA-DR) inflammatory markers in the worst eye, measured at baseline and month 3.

Secondary outcome measures
Efficacy (in worst eye):
1. Global subjective dry eye score (foreign body sensation, dryness, burning, stinging, photophobia)
2. Subjective dry eye score for each symptom
3. Objective dry eye score for each test (fluorescein staining of the cornea, Van Bijsterveld test, tear Break-Up Time [BUT] test, Schirmer-I)
4. Fluorescence intensity of conjunctival cells expressing HLA-DR inflammatory marker
5. Quality of life questionnaire for ocular surface disease

Safety:
6. Adverse or unexpected events

All secondary outcomes were assessed at baseline (D0), week 6 and month 3.

Overall study start date
22/11/2005

Completion date
18/01/2007

Eligibility

Key inclusion criteria
1. Legally adult outpatients, both males and females
2. Having given their written informed consent
3. Suffering from dry eye syndrome as defined by the presence of:
3.1. At least two of the following four objective tests corresponding to the scores below:
3.1.1. Schirmer-I-values less than 10 mm/5 min
3.1.2. Break-up-time-values less than 10 sec
3.1.3. Fluorescein staining of the cornea score greater than or equal to 1 and less than 4
3.1.5. Van Bijsterveld score greater than or equal to 3 and less than or equal to 6 (Lissamine green)
3.2. A score of at least 1, for at least two of the five following subjective tests (scored 0 to 3):

3.2.1. Foreign body sensation
3.2.2. Dryness
3.2.3. Burning
3.2.4. Stinging
3.2.5. Photophobia
4. Stable systemic treatment (unchanged for one month or longer)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
140

Key exclusion criteria
1. Aged less than 18 years
2. Severe dry eye (Lissamine green greater than 6 or corneal staining greater than or equal to 4)
3. Uncontrolled evolutive systemic disease
4. Patients with an implantable cardioverter defibrillator (ICD)
5. Uncontrolled inflammatory disease (treated with varying doses of steroids or non-steroidal anti-inflammatory substances)
6. Change in systemic treatment within the last month
7. Expected change in treatment of concomitant disease
8. Patients treated with anticoagulants or predisposed to bleeding or haemorrhage
9. Drastic change of food and/or food supplements within the last month
10. Other food supplement with eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)
11. Patients with a history of recurrent ocular herpes and/or recurrent uveitis
12. Evidence of acute ocular infection and/or intra-ocular inflammation within one month prior to the onset of this study
13. Patients who have undergone ocular surgery within the last 6 months
14. Change in ocular treatment within the last month
15. Patients currently using any ophthalmic medication including any ocular ointment except artificial tear preparation and eye cleaning solution for treatment of dry eye syndrome
16. Patients treated with topical ocular, steroidal or non-steroidal anti-inflammatory treatment within the last month
17. Patients treated with ocular topical cyclosporin within the last month
18. Occlusion therapy with lacrimal or punctum plugs within the last 3 months
19. Patients currently wearing contact lenses
20. Pregnant or lactating women
21. Women of childbearing potential considering becoming pregnant during the course of the study and those not taking precautions to avoid pregnancy
22. Patients for whom, in the physician's opinion, any of the protocol procedures may pose a special risk not outweighed by the potential benefits of participating in the study
23. Patients who are unlikely to comply with the study protocol or who are likely to be moving and lost to follow-up in the study period
24. Known contraindication, adverse reaction, or hypersensitivity to any constituents of this food

supplement
25. Patients who have participated in any clinical investigation within the last 30 days or are currently participating in a clinical study
26. Patients who are addicted to alcohol or drugs
27. Patients with neurotic, psychiatric disorders or suicidal tendencies
28. Patients who plan to start a diet or to change their diet during the course of the study

Date of first enrolment
22/11/2005

Date of final enrolment
18/01/2007

Locations

Countries of recruitment
France

Italy

Study participating centre
Hôpital Général
Dijon
France
21034

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

Website
http://www.bausch.fr

ROR

https://ror.org/018qejt38

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Laboratoire Chauvin, Bausch & Lomb Inc. (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