

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

<b>Submission date</b> 23/10/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/11/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 02/12/2008	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Catherine Creuzot-Garcher

**Contact details**  
Hôpital Général  
Service d'Ophtalmologie  
3 Rue du Faubourg Raines  
BP 1519  
Dijon  
France  
21034

## Additional identifiers

**Protocol serial number**  
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)

## Primary study design

Interventional

## Study design

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

## Study type(s)

Treatment

## 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(s)

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.

## **Key secondary outcome(s)**

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.

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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)

**ROR**  
<https://ror.org/018qejt38>

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Laboratoire Chauvin, Bausch & Lomb Inc. (France)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration