

# The effect of a unique omega-3 supplement on dry mouth and dry eye in Sjogren's patients

<b>Submission date</b> 07/02/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/03/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 04/11/2008	<b>Condition category</b> Musculoskeletal 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

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Study objectives

Use of omega-3 supplements can increase oral and ocular comfort and increase salivary flow in Sjogren's patients.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Institutional Review Board - Tufts University Health Sciences /Tufts - New England Medical Center on the 16th May 2005 (ref: 7370)

## Study design

Prospective, randomised, placebo-controlled, double-masked clinical trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Sjogren's syndrome

## Interventions

Use of an omega-3 supplement (TheraTears Nutrition, Advanced Vision Research, USA) containing 750 mg of long-chain omega-3s (450 mg of eicosapentaenoic acid [EPA] and 300 mg of docosahexaenoic acid [DHA]) and 1000 mg of flaxseed oil designed to suppress inflammation and increase tear and saliva production.

The participants in the intervention group took the supplement once a day for 3 months.

## Intervention Type

Other

## Phase

Not Specified

**Primary outcome measure**

Increased oral and ocular comfort at 3 months

**Secondary outcome measures**

Increased salivary flow and improvement in gingival index (GI) at 3 months

**Overall study start date**

07/07/2005

**Completion date**

04/09/2007

## Eligibility

**Key inclusion criteria**

Subjects with Sjogren's syndrome as defined by the European Criteria and a positive blood test or lip biopsy

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

65

**Key exclusion criteria**

1. Had less than 10 teeth
2. Received periodontal therapy in the past 12 months or antibiotic therapy in the past 1 month
3. Required pre-medication with antibiotics
4. Had advanced periodontitis, an infectious or wasting disease
5. Already supplementing with omega-3s
6. Participating in another clinical trial

**Date of first enrolment**

07/07/2005

**Date of final enrolment**

04/09/2007

## Locations

**Countries of recruitment**

United States of America

**Study participating centre**  
Tufts University School of Dental Medicine  
Boston  
United States of America  
02111

## **Sponsor information**

### **Organisation**

Advanced Vision Research (USA)

### **Sponsor details**

660 Main St., 1st Floor  
Woburn  
Massachusetts  
United States of America  
01801  
+1 800 231 3316  
jgilbard@theratears.com

### **Sponsor type**

Industry

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Advanced Vision Research (USA)

## **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