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

Submission date	Recruitment status	[ ] Prospectively registered
07/02/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/03/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/11/2008	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Athena Papas

Contact details
Tufts University School of Dental Medicine
One Kneeland Street, Room 508
Boston
United States of America
02111
+1 617 636 3931
athena.papas@tufts.edu

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