Clinical trial on the effect of Resolvis on ocular surface diseases.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26119

Source
NTR

Health condition

dry eye

Sponsors and support

Primary sponsor: Medivis srl, c.so Italia 171, 95127 Catania
Source(s) of monetary or material Support: Medivis srl, c.so Italia 171, 95127 Catania

Intervention

Outcome measures

Primary outcome

Increased stability of the tear film mesured by tear break-up time (BUT).

Secondary outcome

Reduced symptoms (measured by means of a specific questionnaire, ocular surface disease index), and ocular surface signs and inflammation (measured by fluorescin and lissamine green staining of the ocular surface, HLA-DR expression) after treatment of dry eye.

Study description

Background summary

Alterations of the tear film induce ocular surface changes and determine frequent diseases such as dry eye. Omega 3 fatty acid have been demonstrated to be effective in treating dry eye and improving ocular surface conditions when administered orally in humens and topically in a mouse model of dry eye. This study for the first time analyzes the effect of a topical therapy with omega 3 in a double masked randomized clinical trial.

Study objective

The hypothesis of this study is that omega 3 fatty acid in an artificial tear ameliorates symptoms and ocular surface signs in patients with dry eye.

Study design

7 and 28 days.

Intervention

Treatment with Resolvis (bis in die = 2 times/day) for 28 days will be given at the study group (N=15).

The control group (N=15) includes patients with symptoms and signs of dry eye as the treated group, but they will undergo the saline solution with the same posology.

Contacts

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Eligibility criteria

Inclusion criteria

1. Symptoms of dry eye;

2. And at least 2 of the following:

A. Schirmer test < 8mm/5 min;

B. BUT <10 sec;

C. Lissamine green staining > or = 3.

Exclusion criteria

1. Glaucoma;

2. Ocular surface infections;

3. Corneal ulcer;

4. Conjunctival infections;

5. Treatment with anti-inflammatory drugs and cyclosporine in the 3 months preceding the study;

6. Surgical procedures in the 3 months preceding the study;

7. Antiglaucoma therapies;

8. Contact lens use 7 days before the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	14-11-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2995
NTR-old	NTR3143
Other	: MDV0705-010-08
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Rashid S, Jin Y, Ecoiffier T, Barabino S, Schaumberg DA, Dana MR. Topical omega-3 and omega-6 Fatty acids for treatment of dry eye. Arch Ophthalmol 2008;126:219-225.