Ocular inflammation and dry eye.

No registrations found.

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

Summary

ID

NL-OMON26452

Source
NTR

Health condition

dry eye syndrome

Sponsors and support

Primary sponsor: University of Genoa,
viale Benedetto XV, 5, 16132 Genova, Italy, tel. +39-010-3538455

Bausch & Lomb IOM
Dott. Sebastiano Giuffrida
via Senigallia 18
20161 Milano
Source(s) of monetary or material Support: grant from Bausch & Lomb

Intervention

Outcome measures

Primary outcome

Reduced level of expression of HLA-DR after treatment with Loteprednolol etabonate measured by flow cytometry.

Secondary outcome

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

Study description

Background summary

Inflammation plays a pivotal role in dry eye pathogenesis. Recently, it has been demonstrated that specific markers of inflammation such as HLA-DR can be used to monitor the degree of inflammation of ocular surface epithelia. The aim of our project is to test the hypothesis that the use of an anti-inflammatory therapy, Loteprednolol etabonate, can significantly reduce the expression of HLA-DR on conjunctival epithelial cells of patients with dry eye when used for prolonged period of time with tapered doses, compared to artificial tears only.

Study objective

Ocular surface inflammation plays a pivotal role in dry eye. The hypothesis of this study is that markers of inflammation expressed by conjunctival epithelial cells can be used to study inflammation and that the topical use of an anti-inflammatory drug such as Loteprednolol etabonate can reduce the level of ocular surface inflammation in dry eye patients.

Study design

7, 14, 28 and 56 days.

Intervention

Treatment with Loteprednolol etabonate bid (bis in die = 2 times/day) for 14 days, once a day for 14 days and twice a week for 28 days will be given at the study group (N=10).

The control group (N=10) includes patients with symptoms and signs of dry eye as the treated group, but they will undergo the artificial tear (carbossimetilcellulose) with the same posology.

Contacts

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Eligibility criteria

Inclusion criteria

1. Symptoms of dry eye;

2. HLA-DR>15%;

3. And at least 2 of the following:

A. Schirmer test < 8mm/5 min;

B. BUT <10 sec;

C. Lissamine green staining >3.

Exclusion criteria

1. Glaucoma;

2. Ocular surface infections;

3. Corneal ulcer;

4. Conjunctival infections;

5. Treatment with anti-inflammatory drugs 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):	01-01-2010
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion

Date:	15-04-2010
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	NL2167
NTR-old	NTR2291
Other	METC San Martino Hospital and University Clinics, Genoa, Italy : 17/09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A