Clinical trial on the effect of Azyter in patients with blepharitis.

No registrations found.

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

Summary

ID

NL-OMON20089

Source
NTR

Health condition

Blepharitis

Sponsors and support

Source(s) of monetary or material Support: self financing

Intervention

Outcome measures

Primary outcome

Evaluation of HLA-DR expression levels after treatment with Azyter.

Secondary outcome

Symptoms and signs of blepharitis, and level of cytokines in tears after treatment with Azyter.

Study description

Background summary

Blepharitis is a disease of the ocular surface which affects a growing number of patients, and to date there are no definitive treatments available. Inflammation plays a pivotal role in dry eye and possibly in blepharitis. Therefore, we hypothesize that the use of an antibiotic with anti-inflammatory activity may improve symptoms and signs of blepharitis and to reduce the level of ocular surface inflammation mesured as expression of inflammatory cell markers and quantity of inflammatory cytokines in tears.

Study objective

Ocular surface inflammation plays a pivotal role in dry eye and possibly in blepharitis. We hypothesize that the quantity of pro-inflammatory cytokines in tears and the expression of markers of inflammation on conjunctival cells are increased in patients with blepharitis. Furthermore, the aim of our project is to evaluate the effect of topical treatment with Azithromycin on symptoms, clinical signs, and ocular surface inflammation induced by blepharitis.

Study design

7 and 21 days.

Intervention

Treatment with Azyter 2 times/day for 3 days and once/day for 3 days will be given at the study group (N=15).

The control group (N=15) includes patients with symptoms and signs of blepharitis 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 blepharitis;

2. HLA-DR > 15% on conjunctival cells;

3. BUT <10 sec;

4. lid margin hyperemia >=2;

5. Meibum quality >= 10.

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):	15-12-2011
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	12-12-2011
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	NL3044
NTR-old	NTR3192
Other	METC : 9/2011
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Opitz DL, Tyler KF. Efficacy of azithromycin 1% ophthalmic solution for treatment of ocular surface disease from posterior blepharitis.
Clin Exp Optom. 2011 Mar;94(2):200-6.