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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20089

Bron
Nationaal Trial Register

Aandoening

Blepharitis

Ondersteuning

Overige ondersteuning: self financing

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

7 and 21 days.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Viale Benedetto XV, 5
Stefano Barabino
Geneva 16132
Italy

+39 010 35338294

Wetenschappelijk

Viale Benedetto XV, 5
Stefano Barabino
Geneva 16132
Italy
+39 010 35338294

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Symptoms of blepharitis;

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

3. BUT <10 sec;

4. lid margin hyperemia >=2;

5. Meibum quality >= 10.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-12-2011
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-12-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3044
NTR-old	NTR3192
Ander register	METC : 9/2011
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
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.