Ocular inflammation and dry eye.

Gepubliceerd: 15-04-2010 Laatst bijgewerkt: 18-08-2022

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...

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

Samenvatting

ID

NL-OMON26452

Bron
NTR

Aandoening

dry eye syndrome

Ondersteuning

Primaire 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
Overige ondersteuning: grant from Bausch & Lomb

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Reduced level of expression of HLA-DR after treatment with Loteprednolol etabonate

measured by flow cytometry.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

7, 14, 28 and 56 days.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

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 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:	01-01-2010
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

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

Resultaten

Samenvatting resultaten
N/A