The putative role of keratoconjunctivitis sicca in the development of blepharoptosis.

Published: 05-12-2006
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The main objective of this study is to demonstrate whether the number of patients with symptoms of dry eyes is significantly higher in patients with ptosis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular injuries
Study type	Observational non invasive

Summary

ID

NL-OMON30204

Source
ToetsingOnline

Brief title
Dry eyes & ptosis.

Condition

- Ocular injuries

Synonym
drooping eye lid

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis Prof. Dr. H.J. Flieringa.

Intervention

Keyword: aponeurosis, blepharoptosis, keratoconjunctivitis sicca

Outcome measures

Primary outcome

Significant difference in proportion of patients with dry eyes between groups

(*2, α=0.05).

Secondary outcome

Schirmer-2 score, tear break-up time, corneal staining, degree of ptosis,

record of possible risk factors (previous trauma, contact lens wear, ocular

surgery, subjective complaints, punctate keratitis, blepharitis, etc.).

Study description

Background summary

Blepharoptosis (drooping eyelid) can cause loss of visual function. Because surgical correction of the upper eyelid has been shown to significantly improve the visual field, ptosis surgery has become a widely accepted and frequently performed intervention. It is conjectured that prolonged incremental friction between (dry) eye surface and upper eyelid may lead to some degree of mechanical dysintegration of the aponeurosis. Therefore, a dry eye may form an additional risk factor for aponeurotic ptosis. The objective of this study is to determine whether a correlation can be demonstrated between dry eye and ptosis.

Study objective

The main objective of this study is to demonstrate whether the number of patients with symptoms of dry eyes is significantly higher in patients with ptosis.

Study design

Open-label, prospective, single-center. Controls will be matched pairwise with

respect to gender and age to ptosis patients.

Study burden and risks

For patients presenting with complaints of ptosis, this study requires no extra visits and no extra time. All investigational procedures are part of standard medical examination. For controls, measurements will be performed during a single visit which will take approximately 15 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Group 1 (ptosis):

- Diagnosis of gradually developed unilateral or bilateral ptosis of the upper eye lid.
- Age >= 40 years for patients not wearing contact lens(es) in affected eye(s).
- Age >= 20 years for patients wearing contact lens(es) in affected eye(s).
- Vertical eyelid fissure <= 7 mm in primary position.
- Bilateral levator function > 10 mm.;Group 2 (no ptosis):
- Age >= 40 years for patients not wearing contact lens(es).
- Age >= 20 years for patients wearing contact lens(es).
- Vertical eyelid fissure > 7 mm in primary position.
- Bilateral levator function > 10 mm.
- Age and gender match to a patient from group 1 (|*age| < 5 years).

Exclusion criteria

Group 1 (ptosis):
- Neurological disorder.
- Muscular disorder.
- Suspicion of other possible cause.;Group 2 (no ptosis):
- Neurological disorder.
- Muscular disorder.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-04-2007
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	05-12-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL14866.078.06