Sensibility of the upper eyelid after blepharoplasty

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The objective of this study is to find the prevalence and type of sensibility problems after upper blepharoplasty. Also we will study the postoperative course of possible problems in sensibility.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON39022

Source
ToetsingOnline

Brief title
Upper eyelid sensibility

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
Blepharochalasis, drooping upper eyelid

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blepharoplasty, Sensibility, Upper eyelid

Outcome measures

Primary outcome

The primary study parameters are sense of pressure, tactile sensation, temperature and pain.

Also we will look at the time (number of weeks) that has passed between blepharoplasty and the time of testing.

The sense of pressure will be registered as level of pressure (value between 0,5 and 6,0 cm). The sense of tactile sensation, temperature and pain will be registered as intact or disturbed. The results for the sense of pressure will be presented as the average level of pressure. For the sense of tactile sensation, temperature and pain, the percentage of patients whereby the modality is intact will be the primary outcome measure.

Secondary outcome

The age (in years) and sex will be registered for all patients as these variables could possibly influence the recovery of sensibility of the upper eyelid after blepharoplasty. In addition, it will be listed as a patient develops a wound infection or wound healing disorder during the follow-up appointments, because this could affect (the recovery of) the sensiility of the upper eyelid too.

Study description

Background summary

The blepharoplasty is one of the most performed plastic surgery operations. Regularly patients notice a diminishing sensibility of the upper eyelid. The plastic surgeon can often not answer the question how long this loss of sensibility will last and whether it will come back, as little research has taken place in this area. It is assumed that the sensibility of the upper eyelid will be more or less disturbed, and will improve in a period of some weeks to months completely of partly. For providing good pre and post surgical information to the patient concerning the upper eyelid correction it is important to get a better insight in the occurrance of a disturbed sensibility after blepharoplasty, the kind and seriousness, and the duration and degree of recovery.

Study objective

The objective of this study is to find the prevalence and type of sensibility problems after upper blepharoplasty.
Also we will study the postoperative course of possible problems in sensibility.

Study design

The study design is a prospective cohort study during six months.
Patients with blepharochalasis who will have an upper eyelid correction in the Bergman Clinic in Heerenveen, will be approached for participation in the study. The sensibility of their upper eyelid will be tested 4 times, namely one hour before, 1 week after (after removal of the stitches), 6-8 weeks after (when they come for a check up at the OPD) and 6 months after surgery.
The tests will take place in the Bergman Clinic and will last 15-20 minutes each test.

Study burden and risks

The preoperative tests are done one hour before the operation is performed. The tests after one week will take place after the removal of the stitches. The third set of tests will be done when the patient comes for the check up at the OPD after 6-8 weeks. Six months after the upper blepharoplasty, the patient has to come to the Bergman Clinic in Heerenveen solely for the investigation. The tests take place in a room where privacy is guaranteed. Before every test the sensations of the instruments used for the tests will be demonstrated to the patients. The test are not invasive or painful and do not interfere with the treatment that the patient had or will have (blepharoplasty).
The minimal stress caused by the tests is therefore very reasonable in comparison to the benefits the study will have.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with blepharochalasis who will undergo upper eyelid blepharoplasty in the Bergman Clinics Heerenveen between June and September 2012.

Exclusion criteria

Previous surgery on the eyelids.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	10-04-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-04-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22007
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL39947.042.12
OMON	NL-OMON22007