

Upper eyelid sensibility.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22007

Source

NTR

Brief title

BLE-SENS

Health condition

Blepharochalasis
Upper eyelid blepharoplasty, bovenooglid correctie
Sensibiliteit, sensibility
Sensory disturbance, gevoelsstoornis

Sponsors and support

Primary sponsor: University Medical Center Groningen

Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

Perception of touch, temperature, pressure and pain.

Secondary outcome

Age, sex, time between operation and testing and development of an wound infection or wound healing disorder.

Study description

Background summary

For providing good pre and post surgical information to patients concerning upper eyelid blepharoplasty it is important to get a better insight in the occurrence of a disturbed sensibility after upper eyelid blepharoplasty, the kind and seriousness, and the duration and degree of recovery.

Therefore the objective of this study is to get insight of the prevalence, nature and severity of the sensory disturbances that may occur in the skin of the upper eyelid after upper eyelid blepharoplasty, as well as the duration and degree of recovery of them.

Country of recruitment: The Netherlands.

Study objective

It is assumed that the sensibility of the upper eyelid skin will be more or less disturbed after upper eyelid blepharoplasty, and will improve completely or partly in a period of some weeks to months.

Study design

The study design is a prospective cohort study during six months. The sensibility of the upper eyelids will be tested four times, namely one hour before the operation, one week afterwards (after removal of the stitches), 6-8 weeks afterwards (when they came for a check up at the OPD) and six months after the upper eyelid blepharoplasty.

Intervention

All blepharoplasties are performed by using the same standard surgical techniques by one of the four plastic surgeons who work in the Bergman Clinics Heerenveen. Examination of sensibility is divided into the perception of touch, temperature, pressure and pain. These modalities of sensibility are tested by the tip of a cotton ball, a Tip-Therm, a Cochet-Bonnet aesthesiometer and a neurological pin. The tests are performed at three (perceptions of touch and temperature) or six (perceptions of pressure and pain) different places of the upper eyelid skin.

Contacts

Public

University Medical Center Groningen

Department of Plastic, Reconstructive, Aesthetic and Hand Surgery

BB81

PO box 30.001
Shariselle M.W. Pool
Groningen 9700 RB
The Netherlands
+31 (0)50 3613531

Scientific

University Medical Center Groningen

Department of Plastic, Reconstructive, Aesthetic and Hand Surgery

BB81

PO box 30.001
Shariselle M.W. Pool
Groningen 9700 RB
The Netherlands
+31 (0)50 3613531

Eligibility criteria

Inclusion criteria

Patients with blepharochalasis who will have upper eyelid blepharoplasty for that purpose in June, July or August 2012 in the Bergman Clinic in Heerenveen.

Exclusion criteria

Patients who had previous operations on their upper eyelids.

Study design

Design

Study type: Observational non invasive

Intervention model: Parallel

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

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

Ethics review

Positive opinion	
Date:	21-01-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39022
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3643
NTR-old	NTR3798
CCMO	NL39947.042.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39022

Study results

Summary results

N/A