

Upper eyelid sensibility.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22007

Bron

NTR

Verkorte titel

BLE-SENS

Aandoening

Blepharochalasis

Upper eyelid blepharoplasty, bovenooglid correctie

Sensibiliteit, sensibility

Sensory disturbance, gevoelsstoornis

Ondersteuning

Primaire sponsor: University Medical Center Groningen

Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Perception of touch, temperature, pressure and pain.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients who had previous operations on their upper eyelids.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	05-06-2012
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	21-01-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39022
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3643

Register

NTR-old

CCMO

ISRCTN

OMON

ID

NTR3798

NL39947.042.12

ISRCTN wordt niet meer aangevraagd.

NL-OMON39022

Resultaten

Samenvatting resultaten

N/A