

Upper eyelid anesthesia.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22369

Source

NTR

Brief title

BLE-ANES

Health condition

Blepharochalasis; Upper eyelid blepharoplasty; Anesthesia; Prilocaine.
Blepharochalasis; Bovennooglid correctie; Verdoving; Prilocaine.

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)

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

Intervention

Outcome measures

Primary outcome

The pain experienced during infiltration of the anesthetic, will be scored by the participants on a Visual Analogue Scale from 0 to 10, with a score of 0 which means no pain and a score of 10 wich means unbearable pain.

Secondary outcome

The participant will be asked which upper eyelid was more painful during infiltration of the anesthetic: the first (right) upper eyelid, the second (left) upper eyelid, or no difference between the two upper eyelids. Besides that, the plastic surgeon will record for each upper eyelid the number of times that reinjection of anesthetic was needed during the operation (0x, 1x, 2x, etc.).

Study description

Background summary

The aim of this study is to investigate whether infiltration of the upper eyelid with Citanest is less painful than infiltration of the upper eyelid with Xylocaine. If this hypothesis proves to be correct, then in the future Citanest can be used in every upper eyelid blepharoplasty in order to reduce the pain on infiltration of the upper eyelids.

Study objective

Injecting the upper eyelids with the anesthetic is experienced as quite painful by most patients. The acidity of the commonly used anesthetic Xylocaine is assumed to be the (main) cause of the pain. Citanest, the standard local anesthetic in dentistry, has a higher pH than Xylocaine and could therefore lead to less pain during stunning of the upper eyelids in upper eyelid blepharoplasty.

Study design

After injection of each upper eyelid, the participant will be asked to score the pain experienced on infiltration. So this will be asked twice in total (on the day of operation).

Intervention

All blepharoplasties will be performed by one of four plastic surgeons who work in the Bergman Clinics. In all participants one of the upper eyelids will be stunned 'standard' with Xylocaine 1%-Adrenaline (lidocaine hydrochloride 10 mg/ml with epinephrine 5 µg/ml). The other upper eyelid will be injected with Citanest 3%-Octapressine (prilocaine hydrochloride 30 mg/ml with felypressine 0,54 µg/ml). Drawing lots just before the operation will determine which upper eyelid will be injected with Xylocaine and which upper eyelid with Citanest.

For stunning, a 10 cc syringe is used with a 30G needle. Both anesthetics will be at room temperature, and are injected with a similar speed. In all participants, a volume of about 5 ml will be injected in each upper eyelid. If additional anesthetic is required or necessary during the operation, this will be provided by the same anesthetic which is used initially.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with blepharochalasis, who will have an upper eyelid blepharoplasty for that purpose in the Bergman Clinics Heerenveen or Zwolle upward of the 1st of July 2013.

Exclusion criteria

Previous surgery on the upper eyelids, hypersensitivity to any component of Xylocaine 1%-Epinephrine or Citanest 3%-Octapressin or other local anesthetics of the amide type, congenital or idiopathic methaemoglobinaemia or inability to score pain using a Visual Analogue Scale (from 0 to 10).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2013
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion	
Date:	10-02-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39724
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3677

Register

NTR-old

CCMO

ISRCTN

OMON

ID

NTR3847

NL41653.042.12

ISRCTN wordt niet meer aangevraagd.

NL-OMON39724

Study results

Summary results

N/A