Anesthesia of the upper eyelid in upper blepharoplasty

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

Summary

ID

NL-OMON39724

Source
ToetsingOnline

Brief title
Anesthesia upper eyelid

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: Anesthesia, Blepharoplasty, Prilocaine, Upper eyelid

Outcome measures

Primary outcome

The pain experienced during infiltration of the anesthetic, has been 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 is 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.

- The plastic surgeon will record for each upper eyelid the number of times that reinjection of anesthetic was needed during the operation, written as 0x, 1x, 2x, etc.

- The plastic surgeon will also record which of the upper eyelids did bleed more during surgery (right, left of no difference) and how much swelling (no, slight, moderate of severe), redness (no, slight, moderate of severe) and/or blue discoloration (no, minimal, moderate, severe) of the upper eyelids was seen just after the operation.

Study description

Background summary

Upper blepharoplasty is one of the most commonly performed procedures by plastic surgeons. 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.
Citanest, the standard local anesthetic in dentistry, has a higher pH then Xylocaine and could therefore lead to less pain during stunning of the upper eyelids in upper blepharoplasty.

Study objective

The aim of this study is to investigate whether infiltration of the upper eyelid with Citanest is less painful then 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 blepharoplasty in order to reduce pain on infiltration.

Study design

The study involves a patient-blinded randomized controlled trial.
All patients with blepharochalasis, who will have upper blepharoplasty in the Bergman Clinics Heerenveen or Zwolle upward to the 1st of November 2013, will be asked to participate in this study. When consent is obtained, drawing lots just before the operation will determine which upper eyelid will be injected with Xylocaine and which upper eyelid with Citanest. After injection of each upper eyelid to the participant will be asked to score the pain experienced on infiltration using a Visual Analogue Scale from 0 to 10, where 0 means no pain and 10 means unbearable pain.
In addition, the participant is asked whether the pain on both upper eyelids during infiltration of the anesthetic was similar whether the first (right) or second (left) upper eyelid was more painful.
Finally, after the operation, the plastic surgeon will note if there was any need to reinject one or both upper eyelid(s) during the procedure.

Intervention

In all participants one of the upper eyelids will be stunned 'standard' with 5 ml Xylocaine 1%-Adrenaline (lidocainehydrochloride 10 mg/ml with epinephrine 5 µg/ml). The other upper eyelid will be injected with 5 ml Citanest %-Octapressine (prilocainehydrochloride 30 mg/ml with felypressine 0,54 µg/ml). If additional anesthetic is required or neccesary during the operation, this is provided by the same anesthetic which was used initially.
For stunning, a 10 cc syringe is used with a 30G needle. Both anesthetics are at room temperature, and are injected with a similar speed. In all

participants, a volume of about 5 ml is injected in each upper eyelid.

Study burden and risks

No burden or time load is associated with participation in the study. After injection of each upper eyelid, the participant will be asked to score the pain experienced on infiltration using a Visual Analogue Scale from 0 to 10. So this will be asked twice in total. In addition, the participant is asked once (afterwards) whether the pain of both upper eyelids during infiltration of the anesthetic was similar whether the first or second upper eyelid was more painful.
Participation in the study does not affect the upper blepharoplasty that the participant will have. Participants do not need to visit the clinic especially for the study. In all participants one of the upper eyelids will be stunned with the standard anaesthetic Xylocaine, while the other upper eyelid will be injected with Citanest. It is possible that participants experience less pain at the infiltration of one of the two upper eyelids. No adverse effects are known of injecting the upper eyelid with Citanest.

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

Patients with blepharochalasis who will have upper eyelid blepharoplasty for that purpose in the Bergman Clinics Heerenveen or Zwolle upward of the 1st of November 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
- Inability to score pain using a Visual Analogue Scale

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	01-02-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-12-2013
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: 22369
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL41653.042.12
OMON	NL-OMON22369