Upper eyelid anesthesia.

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22369

Bron
NTR

Verkorte titel
BLE-ANES

Aandoening

Blepharochalasis; Upper eyelid blepharoplasty; Anesthesia; Prilocaine.
Blepharochalasis; Bovenooglid correctie; Verdoving; Prilocaïne.

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)
Overige ondersteuning: University Medical Center Groningen (UMCG)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 eyelid blepharoplasty in order to reduce the pain on infiltration of the upper eyelids.

Doel van het onderzoek

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 then Xylocaine and could therefore lead to less pain during stunning of the upper eyelids in upper eyelid blepharoplasty.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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 (lidocainehydrochloride 10 mg/ml with epinephrine 5 µg/ml). The other upper eyelid will be injected with Citanest 3%-Octapressine (prilocainehydrochloride 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 neccesary during the operation, this will be provided by the same anesthetic which is used initially.

Contactpersonen

Publiek

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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 an upper eyelid blepharoplasty for that purpose in the Bergman Clinics Heerenveen or Zwolle upward of the 1st of July 2013.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2013
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39724
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3677
NTR-old	NTR3847
CCMO	NL41653.042.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Register	ID
OMON	NL-OMON39724

Resultaten

Samenvatting resultaten
N/A