Lateral eyelid block excision versus lateral tarsal strip procedure.

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Lateral eyelid block excision is not inferior to lateral tarsal strip procedure.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20295

Bron
NTR

Verkorte titel
N/A

Aandoening

Ectropion
Entropion
Facial palsy
Eyelid laxity due to ocular prosthesis wear

Ondersteuning

Primaire sponsor: Universitair Medisch Centrum Utrecht, Oogheelkunde

Het Oogziekenhuis Rotterdam
Overige ondersteuning: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Surgical success at one year, defined as restoration of the lower eyelid position at the midline through the pupillary center and at the lateral canthus, without in- or outward rotation of the lower eyelid margin.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
The lateral tarsal strip procedure is a successful and widely used technique to correct horizontal eyelid laxity in, among others, ectropion, entropion, and facial palsy. Lateral eyelid block excision is a less well known technique to correct horizontal eyelid laxity with probably the same success rate but with less complexity to perform.

Objective:
To show non-inferiority in success rate of the lateral eyelid block excision compared to the lateral tarsal strip.

Study design:
Randomized controlled non-inferiority trial with masking of the assessor of the primary and secondary outcomes.

Study population:
Patients with horizontal eyelid laxity for which surgical intervention is planned in two tertiary referral centres in the Netherlands. Conditions with horizontal eyelid laxity include: entropion, ectropion, sagging secondary to an anophthalmic socket, facial palsy, and scleral show following blepharoplasty. Horizontal laxity is considered significant if there is an abnormal snap-back test and a malposition of the lower eyelid.

Intervention:
Group 1: lateral tarsal strip procedure with permanent suture. Group 2: lateral eyelid block excision with absorbable suture.

Main study parameters/endpoints:
Surgical success at one year, defined as restoration of the lower eyelid position at the midline through the pupillary center and at the lateral canthus, without in- or outward rotation of the lower eyelid margin.
Secondary study parameters: Complication rate (suture abscess/granuloma, exposed suture, point tenderness over lateral orbital rim, and wound dehiscence). Surgery time.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Both surgical procedures are accepted and practiced treatments to correct for horizontal eyelid laxity. They bear the same, limited, risks of postoperative bleeding, pain, inflammation and failure rate. The burden for patients related to participation in the study is a more extensive physical examination, informed consent procedure and questionnaires (10

minutes) and an extra one year follow-up appointment (10 minutes, excluding travelling time). Because of the non-inferiority design, there are no expected benefits in surgical successes. However, benefits for the lateral eyelid block excision group are anticipated in shorter surgery time and less suture-related complications.

Doel van het onderzoek

Lateral eyelid block excision is not inferior to lateral tarsal strip procedure.

Onderzoeksopzet

Preoperative, peroperative, 2 months, 12 months.

Onderzoeksproduct en/of interventie

1. Lateral eyelid block excision;

2. Lateral tarsal strip procedure.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients who have an eyelid condition for which a surgical procedure is planned that includes lateral horizontal eyelid tightening. The conditions include: ectropion, entropion, facial palsy, eyelid laxity due to ocular prosthesis wear.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age under 18 years;

2. Surgical procedures that also include medial horizontal eyelid tightening;

3. Cicatricial diseases causing eyelid malposition;

4. Cosmetic blepharoplasty.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2009
Aantal proefpersonen:	164
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	02-02-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1574
NTR-old	NTR1653
Ander register	OZR/NL : 2008-16/24391.078.08
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A