Lateral eyelid block excision versus lateral tarsal strip procedure.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20295

Source
NTR

Brief title
N/A

Health condition

Ectropion
Entropion
Facial palsy
Eyelid laxity due to ocular prosthesis wear

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht, Oogheelkunde

Het Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis

Intervention

Outcome measures

Primary outcome

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 outcome

1. Horizontal eyelid laxity (snap-back test);

2. Complications, defined as any of suture abscess/granuloma, exposed suture, point tenderness or redness over lateral canthus persistent after two months, conjunctival inclusion cysts, and wound dehiscence;
3. Surgery time.

Study description

Background summary

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.

Study objective

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

Study design

Preoperative, peroperative, 2 months, 12 months.

Intervention

1. Lateral eyelid block excision;

2. Lateral tarsal strip procedure.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. Age under 18 years;

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

3. Cicatricial diseases causing eyelid malposition;

4. Cosmetic blepharoplasty.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2009

Enrollment:	164
Type:	Actual

Ethics review

Positive opinion Date:	02-02-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results
N/A