LATERAL EYELID BLOCK EXCISION VERSUS LATERAL TARSAL STRIP PROCEDURE TO CORRECT FOR HORIZONTAL EYELID LAXITY

Published: 13-01-2009
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To show non-inferiority in success rate of the lateral eyelid block excision compared to the lateral tarsal strip.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders NEC
Study type	Interventional

Summary

ID

NL-OMON32828

Source
ToetsingOnline

Brief title
Lateral eyelid block excision versus lateral tarsal strip procedure

Condition

- Eye disorders NEC

Synonym
en/ectropion, horizontal eyelid laxity

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Flieringa Stichting

Intervention

Keyword: eyelid, horizontal laxity, surgery

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

Complication rate (suture abscess/granuloma, exposed suture, point tenderness

over lateral orbital rim, and wound dehiscence). Surgery time.

Study description

Background summary

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.

Study 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.

Intervention

Group 1: lateral tarsal strip procedure with permanent suture. Group 2: lateral

eyelid block excision with absorbable suture.

Study burden and risks

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.

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 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

Age under 18 years.
Surgical procedures that also include medial horizontal eyelid tightening.
Cicatricial diseases causing eyelid malposition
Cosmetic blepharoplasty

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-06-2009
Enrollment:	164
Type:	Actual

Ethics review

Approved WMO

Date:	13-01-2009

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL24391.078.08