Continuation of platelet inhibiting drugs in eyelid surgery.
A randomized, double-masked, placebo-controlled clinical trial.

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To demonstrate non-inferiority of continuation of platelet inhibiting drugs in eyelid surgery regarding the risk of haemorrhagic complications.

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

Summary

ID

NL-OMON33474

Source
ToetsingOnline

Brief title
Platelet inhibiting drugs in eyelid surgery

Condition

- Eye disorders NEC
- Eye therapeutic procedures

Synonym
bleeding, haemorrhagic complications in oculoplastic surgery

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam

Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis (SWOO)

Intervention

Keyword: Eyelid surgery, Haemorrhagic complications, Platelet inhibitors

Outcome measures

Primary outcome

Peroperative bleeding

Postoperative bleeding

Postoperative bruising

Secondary outcome

Retrobulbar haemorrhage

Result of surgery

Duration of surgery

Cardiac or cerebral ischaemic event

Study description

Background summary

Retrobulbar bleeding can cause total functional loss of the eye. In order to reduce that risk, antiplatelet medication is commonly discontinued perioperatively in oculoplastic surgery. This practise may have to be reconsidered, however, because 1) the incidence of serious haemorrhagic complications may be low and 2) the risk of serious systemic ischaemic events is temporarily increased. Prospective studies are needed to develop evidence-based guidelines for the use of platelet inhibiting drugs in combination with oculoplastic surgery.

Study objective

To demonstrate non-inferiority of continuation of platelet inhibiting drugs in

eyelid surgery regarding the risk of haemorrhagic complications.

Study design

Prospective, double-masked, randomized, placebo-controlled trial.

Intervention

Continuation (group 1) or discontinuation (group 2) of platelet inhibiting drugs.

Study burden and risks

Participants of group 2 will be subject to the current procedure for eyelid surgery in The Rotterdam Eye Hospital. Therefore, no additional risk is involved. Patients of group 1 may be subject to a lower relative risk of ischaemic events and higher relative risk of haemorrhagic events due to eyelid surgery. Burden is low (two extra visits which take about 10-15 minutes each).

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

daily use of acetylsalicylic acid or carbasalate calcium
scheduled for surgical correction of ectropion or entropion, or for non-cosmetic upperlid blepharoplasty without fat excision

Exclusion criteria

concomitant use of other anticoagulant drugs (coumarin derivatives, clopidogrel, dipyridamol, NSAIDs)
known systemic disease that affects haemostasis
prescribing physician advising against discontinuation
obvious fat prolapses that need to be excised in case of blepharoplasty.
general anaesthesia

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	26-10-2009
Enrollment:	324
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	aspirin
Generic name:	acetylsalicylic acid
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	29-04-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-06-2009
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
EudraCT	EUCTR2009-009986-32-NL
CCMO	NL26858.078.09