Efficacy of Arnica D1 ointment after upper blepharoplasty: a randomized, double-blind, placebo-controlled study

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To evaluate the efficacy of Arnica om postoperative outcome after upper blepharoplasty.

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON37889

Source
ToetsingOnline

Brief title
Efficacy of Arnica ointment after blepharoplasty

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
'blepharoplasty' and 'upper eyelid reduction'

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: lokaal wetenschappelijk fonds (ZWIK): ten behoeve van reiskostenvergoeding voor deelnemende patiënten

Intervention

Keyword: Arnica, blepharoplasty, ecchymosis, hematoma

Outcome measures

Primary outcome

The overall judgment of an unrelated, uninvolved, and blinded-to-treatment plastic surgeon, at week 1 and 6 after blepharoplasty. This plastic surgeon will score both eyelids for the amount of swelling, ecchymosis, redness. On basis of these data, he/she will come to a judgment as to whether one of the eyelids has achieved a superior outcome (eg, no difference vs. left eyelid looks superior vs. righht eyelid looks superior). When a mark of superior outcome coincides with an eyelid of treatment, this is considered a positive treatment outcome.

Secondary outcome

Intra-individuel differences between eyelids, with regard to redness, ecchymosis, swelling and pain (day 3, week 1 and week 6), patients satisfaction with postoperative recovery (week 6) and patient satisfacton with regard to postoperative outcome (week 6).

Study description

Background summary

• Arnica is currently used in homeopathic preparations for strains and bruises.
• Some plastic surgeons advise patients undergoing blepharoplasty to use Arnica in order to prevent postoperative ecchymosis
• No decent study evaluated the efficacy of topical Arnica ointment after upper blepharoplasty.

Study objective

To evaluate the efficacy of Arnica om postoperative outcome after upper blepharoplasty.

Study design

• Monocenter study: department of plastic surgery, Isala Klinieken Zwolle
• Prospective, randomized, double-blind, placebo-controlled
• Surgeons: plastic surgeons and residents in plastic surgery with expertise in blepharoplasty (record of at least 30 upper blepharoplasties).
• Operative procedure: standardized blepharoplasty pocedure

Intervention

• Two study arms:
1. Application of Arnica ointment to one eyelid, and no treatment of the other eyelid
2. Application of Placebo ointment to one eyelid, and no treatment of the other eyelid
• Treatment: periorbital application of Arnica or placebo ointment (double-blind) to one eyelid twice a day, on day 0, 1, 2, 3, 4, 5, 6 (with *0* being day of surgery)

Study burden and risks

Study participants are exposed to an extra 5-15 minutes in their preoperative counseling consult. Moreover, they undergo two additional checkings of 15 minutes (to complete a questionnaire and to take light photographs).
There is an additional 5-15 minutes at the time of operation, to allow for completing a questionnaire.
Study-related risks:
- Increased risk of pain as a consequence of applying ointment to a recently operated area.
- (Minimally) increased risk of infection as a consequence of applying ointment to a recently operated area

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

All patients undergoing a primary upper blepharoplasty, aged 18 years or older.

Exclusion criteria

Use of anticoagulant medication.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-11-2012
Enrollment:	136
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Weleda Arnica Zalf
Generic name:	Weleda Arnica Zalf
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	19-11-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	EUCTR2012-000847-28-NL
CCMO	NL39916.075.12
Other	NTC01598909