The effect of lidocaine temperature on pain perception during infiltration for upper blepharoplasty: a blinded randomised trial comparing 21°C and 32°C solutions

Published: 04-03-2019
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To evaluate the effect of lidocaine temperature on pain perception during infiltration for upper blepharoplasty.

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

Summary

ID

NL-OMON49046

Source
ToetsingOnline

Brief title
The effect of lidocaine temperature on pain perception

Condition

- Eye disorders NEC

Synonym
bilateral blepharoptosis, drooping eyelids

Research involving
Human

Sponsors and support

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

Intervention

Keyword: lidocaine, local anesthesia, temperature, upper eyelid surgery

Outcome measures

Primary outcome

Pain during infiltration on a visual analogue scale.

Secondary outcome

Time course lidocaine preparation

Study description

Background summary

It has been reported that warming a local anaesthetic reduces pain during infiltration.

Study objective

To evaluate the effect of lidocaine temperature on pain perception during infiltration for upper blepharoplasty.

Study design

Randomised, comparative, single blinded study.

Intervention

Patients will be randomized between warm (32°C) versus ambient temperature (21°C) anaesthetic solutions for infiltration in eyelid surgery.

Study burden and risks

Risks are negligible.

Contacts

Public
Oogziekenhuis Rotterdam

Schiedamse Vest 180
Rotterdam 3011 BH
NL
Scientific
Oogziekenhuis Rotterdam

Schiedamse Vest 180
Rotterdam 3011 BH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age * 18 years
Bilateral upper blepharoplasty

Exclusion criteria

Previous surgical intervention to the eyelid(s)
Hypersensitivity to any of the contents of the local anaesthetic
Anxiety which requires tranquilizing or sedative agents prior to administering the local anaesthetic

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-02-2020
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO Date:	04-03-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-11-2022
Application type:	Amendment
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

ID: 19869
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL67490.078.18
OMON	NL-OMON19869