Clonidine as an adjuvant to prolong local anaesthesia in ophthalmic surgery with cryocoagulation. A randomized, controlled, double-blind trial.

Published: 10-12-2010
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To determine the beneficial effect of a single dose of 150 µg clonidine as an adjuvant to chirocaine in retrobulbar block.

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

Summary

ID

NL-OMON36352

Source
ToetsingOnline

Brief title
Retrobulbar clonidine

Condition

- Eye disorders NEC

Synonym
Rhegmatogenous retinal detachment & glaucoma requiring cryocoagulation

Research involving
Human

Sponsors and support

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

Oogziekenhuis - Prof. Dr. Flieringa (SWOO)

Intervention

Keyword: Clonidine as adjuvant, Cryocoagulation, Post-operative pain reduction, Retrobulbar block

Outcome measures

Primary outcome

Maximal pain level, time of maximal post-operative pain, amount of escape

medication used, time of use.

Secondary outcome

Serum level of clonidine at 30, 60, 90 and 240 minutes after retrobulbar

injection, and at postoperative day.

Study description

Background summary

Clonidine, as an adjuvant in neuraxial local anaesthesia, is generally recognized to prolong motor block and analgesia. It is conjectured to have a similar effect on peripheral nerves and, thus, might help to reduce post-operative pain and use of analgesics.

Study objective

To determine the beneficial effect of a single dose of 150 µg clonidine as an adjuvant to chirocaine in retrobulbar block.

Study design

Randomized, controlled, double-blind trial.

Intervention

Retrobulbar injection of 150 µg clonidine.

Study burden and risks

Participants receiving clonidine (group 2) may benefit from reduced pain. Burden of participants is negligible and study-related extra time is about 10 minutes. We anticipate the risk of side effects of retrobulbar administration of clonidine to be limited.

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

- Age >= 18 years.
- Informed consent.
- Rhegmatogenous retinal detachment requiring cryocoagulation and episcleral explant.

- Glaucoma requiring cryocoagulation of the ciliary body.

Exclusion criteria

- Hypersensitivity to clonidine or any other ingredients in the product.
- Severe bradyarrhythmia as a result of sick sinus syndrome or 2nd or 3rd degree AV block.
- Use of oral clonidine.
- Lapp lactase deficiency or glucose-galactose malabsorption.
- Bipolar disorder.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-07-2011
Enrollment:	108
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Catapresan
Generic name:	clonidine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	10-12-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-03-2011
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	EUCTR2010-024100-10-NL
Other	NA
CCMO	NL34843.078.10