Clonidine als toevoeging voor de verlenging van pijnbestrijding bij oogoperaties.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25087

Source
NTR

Brief title
NA

Health condition

Anaesthesia for patients scheduled for retinal cryocoagulation and episcleral explant, or cryocoagulation of ciliary body.

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam (OZR)
Postbus 70030
3000 LM, Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis

Intervention

Outcome measures

Primary outcome

1. Maximal pain level (VAS-score);

2. Time of maximal post-operative pain;

3. Amount of escape medication used;

4. Time of use.

Secondary outcome

1. Pharmacokinetics of clonidine will be investigated in 4 men and 4 women;

2. Serum level of clonidine (LC-MS/MS) at 30, 60, 90 and 240 minutes after retrobulbar injection, and at postoperative day. Detection limit will be at least 0.1 µg/l.

Study description

Background summary

Rationale:

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.

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.
Study population: Patients with indication for retinal cryocoagulation and episcleral explant, or cryocoagulation of ciliary body.

Intervention:

Retrobulbar injection of 150 µg clonidine.

Main study parameters:

Maximal pain level, time of maximal post-operative pain, amount of escape medication used, time of use.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

Study objective

Clonidine as an adjuvant in retrobulbar block reduces post-operative pain and use of analgesics.

Study design

Primary parameters: 2 and 5 hours postop, bedtime at day of surgery, postop day 1.

Secondary parameters: 30, 60, 90 and 240 minutes after retrobulbar injection, and at postoperative day.

Intervention

The investigational product of this study is clonidine, which will be used as an adjuvant in retrobulbar block. The efficacy of clonidine will be compared with a control group.

Group 1: Retrobulbar, Chirocaine 7.5 mg/ml: 3-5 ml;

Group 2: Retrobulbar, Chirocaine 7.5 mg/ml: 3-5 ml + clonidine 150 µg in 1 ml.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age ≥ 18 years;

2. Informed consent;

3. Rhegmatogenous retinal detachment requiring cryocoagulation and episcleral explant;

4. Glaucoma requiring cryocoagulation of the ciliary body.

Exclusion criteria

1. Hypersensitivity to clonidine or any other ingredients in the product;

2. Severe bradyarrhythmia as a result of sick sinus syndrome or 2nd or 3rd degree AV block;

3. Use of oral clonidine;

4. Lapp lactase deficiency or glucose-galactose malabsorption;

5. Bipolar disorder;

6. History of renal insufficiency.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2011
Enrollment:	108
Type:	Actual

Ethics review

Positive opinion

Date:	24-03-2011
Application type:	First submission

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
NTR-new	NL2690
NTR-old	NTR2820
Other	Oogziekenhuis Rotterdam / CCMO : OZR-2010-17 / NL34843.078.10;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Górniak M, Proost JH, Veckeneer M, Mulder VC, Wubbels RJ.
Clonidine as an adjuvant to prolong local analgesia in conventional scleral buckle surgery.
J Ocul Pharmacol Ther. 2014; Sep 4 [Epub ahead of print].
PubMed PMID: 25188774