Clonidine als toevoeging voor de verlenging van pijnbestrijding bij oogoperaties.

Gepubliceerd: 24-03-2011 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25087

Bron
NTR

Verkorte titel
NA

Aandoening

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

Ondersteuning

Primaire sponsor: Oogziekenhuis Rotterdam (OZR)
Postbus 70030
3000 LM, Rotterdam
Overige ondersteuning: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Maximal pain level (VAS-score);
2. Time of maximal post-operative pain;
3. Amount of escape medication used;
4. Time of use.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age ≥ 18 years;

2. Informed consent;

3. Rhegmatogenous retinal detachment requiring cryocoagulation and episcleral explant;

4. Glaucoma requiring cryocoagulation of the ciliary body.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2011
Aantal proefpersonen:	108
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	24-03-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2690

Register	ID
NTR-old	NTR2820
Ander register	Oogziekenhuis Rotterdam / CCMO : OZR-2010-17 / NL34843.078.10;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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