Ibopamine eye drops in the treatment of hypotony after vitreoretinal surgery in retinal detachment or uveitis

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/12/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/12/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
04/11/2008	Eve Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

OZR-2002-17; NTR187

Study information

Scientific Title

Study objectives

Administration of Ibopamine hydrochloride eye drops restores intraocular pressure in patients with hypotony following vitreoretinal surgery or uveitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised, single blinded, placebo controlled, crossover trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Ocular hypotony following either vitreoretinal surgery or uveitis

Interventions

Treatment with ibopamine hydrochloride (0.5 % or 2%) eye drops or placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ibopamine hydrochloride

Primary outcome measure

Ocular pressure on treatment day

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/01/2003

Completion date

01/04/2003

Eligibility

Key inclusion criteria

- 1. Hypotony (0 5 mmHg)
- 2. Stable eye pressure for at least 4 months
- 3. No reaction of eye pressure to atropine and steroids
- 4. Continued steroid treatment during past six months
- 5. Status after vitreoretinal surgery or uveitis

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

15 (study completed)

Key exclusion criteria

- 1. Chronic heart failure
- 2. Traction on corpus ciliare
- 3. Cyclodialysis

Date of first enrolment

01/01/2003

Date of final enrolment

01/04/2003

Locations

Countries of recruitment

Netherlands

Study participating centre

Oogziekenhuis Rotterdam

Rotterdam Netherlands 3011 BH

Sponsor information

Organisation

Rotterdam Eye Hospital (Oogziekenhuis Rotterdam) (The Netherlands)

Sponsor details

Schiedamsevest 180 Rotterdam Netherlands 3011 BH +31 (0)10 401 77 77 info@oogziekenhuis.nl

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/02hjc7j46

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Foundation of Scientific Research at the Eye Hospital (Stichting Wetenschappelijk Onderzoek het Oogziekenhuis) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/03/2006		Yes	No