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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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 summary

Not 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