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Ibopamine 2% eye drops in the treatment of patients with ocular hypotony after vitreoretinal surgery for retinal detachment or uveitis: results after six months of treatment

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
12/04/2021

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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-2003-16

Study information

Scientific Title
Ibopamine 2% eye drops in the treatment of patients with ocular hypotony after vitreoretinal surgery for retinal detachment or uveitis: results after six months of treatment

Study objectives
Long-term administration of Ibopamine hydrochloride eye drops restores and maintains intraocular pressure in patients with hypotony following vitreoretinal surgery for ablatio reinae, or uveitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non-randomised trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Ocular hypotony following either vitreoretinal surgery or uveitis

Interventions
Long-term topical treatment with Ibopamine (2%) eye drops.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Ibopamine

Primary outcome measure
1. Ocular pressure
2. Vision

Secondary outcome measures
1. Position of silicone oil (after surgery)
2. Patients comfort/pain five minutes after eye drops administration

Overall study start date
01/03/2004

Completion date
01/03/2006

Eligibility

Key inclusion criteria
1. Hypotony (0-5 mm Hg)
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
Not Specified

Sex
Both

Target number of participants
21 (Study closed, analysis & publication in progress)

Total final enrolment
17

Key exclusion criteria
1. Chronic heart failure
2. Hypotony caused by other factors than surgery or uveitis
3. Traction on corpus ciliare
4. Cyclodialysis

Date of first enrolment
01/03/2004

Date of final enrolment

01/03/2006

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
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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		01/04/2012	12/04/2021	Yes	No