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Effect of prophylactic Brimonidine instillation on bleeding during Strabismus surgery in adults

Submission date	Recruitment status	[_] Prospectively registered
03/04/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/04/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/08/2008	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
1

Study information

Scientific Title

Acronym
BS

Study objectives
Topical brimonidine administration before strabismus surgery reduced intraoperative bleeding and postoperative subconjunctival haemorrhage in adult patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
There was no Institutional Review Board (IRB) at the time of studying. The IRB of our institute was established in 2006, but this study was performed from 2004 to 2005, and our IRB does not approve already completed studies.

All participants understood the procedure exactly and gave informed consent, and the Helsinki declaration and all federal laws were followed.

Study design
Randomised comparative interventional case series

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Strabismus

Interventions
Patients were instilled with either a single drop of brimonidine-purite 0.15%, phenylephrine 1% or sodium hyaluronate 0.1% 15 minutes prior to strabismus surgery.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Brimonidine, phenylephrine, sodium hyaluronate

Primary outcome measure
Intraoperative bleeding and postoperative subconjunctival haemorrhage were graded on a scale of one to three. Intraoperative bleeding was scored during the surgery, postoperative subconjunctival haemorrhage was graded four hours after surgery.

Secondary outcome measures
Cardiovascular complications and angle-closure glaucoma attack were reported during all follow up periods.

Overall study start date
10/01/2004

Completion date
04/05/2007

Eligibility

Key inclusion criteria
Adult patients who underwent strabismus surgery under topical anaesthesia.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90

Key exclusion criteria
Patients who had received prior ocular surgery were excluded.

Date of first enrolment
10/01/2004

Date of final enrolment
04/05/2007

Locations

Countries of recruitment
Korea, South

Study participating centre
Institute of Vision Research
Seoul
Korea, South
135-720

Sponsor information

Organisation
Yonsei University College of Medicine (South Korea)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01wjejq96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Yongdong Severance Hospital (South Korea)

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	01/09/2007		Yes	No