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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
03/04/2007		☐ 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

Contact name

Dr Sueng-Han Han

Contact details

Institute of Vision Research
Department of Ophthalmology
Yongdong Severance Hospital
Yonsei University College of Medicine
146-92 Dokok-dong
Kangnam-gu
Seoul
Korea, South
135-720
+82 (0)2 2019 3440
samini@yumc.yonsei.ac.kr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

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)

Sponsor details

146-92 Dogok-dong Kangnam-gu Seoul Korea, South 135-720 samini@yumc.yonsei.ac.kr

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