Comparison of the effects of sevoflourane and ketamine on intraocular pressure (IOP) in healthy patients and patients with glaucoma

Submission date Recruitment status Prospectively registered 18/10/2005 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 16/11/2005 Completed [] Results Individual participant data Last Edited Condition category Record updated in last year 21/09/2007 **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

N/A

Study information

Scientific Title

Study objectives

Glaucoma is a slowly progressive optic neuropathy which may rarely be seen in children, and is a leading cause of visual loss in adults. The effects of ketamine and sevoflourane, two commonly used anesthetic agents, on intraocular pressure, are not well known. Serial measurements of IOP in patients randomised to one of the two anesthetic agents will be evaluated. Eyes may be glaucomatous or healthy. Confounding variables, including pulse, blood pressure, oxygenation, will be recorded and evaluated.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Glaucoma

Interventions

Intraocular pressure measurements will be recorded in patients with glaucoma and in healthy patients.

Both sevoflourane and ketamine are commonly used anaesthetic agents. Patients will be randomised to one of the two groups unless the anaesthesiologist or patient prefer one of the agents.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sevoflourane and ketamine

Primary outcome measure

Change in intraocular pressure after administration of anesthetic agent:

- 1. How greatly does the IOP change?
- 2. What percentage of patients in each group have a statistically significant change?

Secondary outcome measures

Effect of pulse, blood pressure, oxygenation, baseline IOP, baseline eye disease on intraocular pressure.

Overall study start date

01/01/2005

Completion date

30/12/2005

Eligibility

Key inclusion criteria

Patients undergoing general anesthesia.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Key exclusion criteria

- 1. Patients unwilling/unable to give informed consent
- 2. Patients with irregular corneas or other ocular abnormalities not allowing for an adequate IOP measurement

Date of first enrolment

01/01/2005

Date of final enrolment

30/12/2005

Locations

Countries of recruitment

United States of America

Study participating centre 600 N. Wolfe Street

Baltimore United States of America 21287

Sponsor information

Organisation

Wilmer Eye Institute (USA)

Sponsor details

600 N. Wolfe Street Baltimore United States of America 21287 +1 410 614 5561 ncongdon@jhmi.edu

Sponsor type

Research organisation

ROR

https://ror.org/05cb1k848

Funder(s)

Funder type

Research organisation

Funder Name

Wilmer Eye Institute (USA)

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