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

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

Organisation
Wilmer Eye Institute (USA)

Sponsor details
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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