ISRCTN73431052 https://doi.org/10.1186/ISRCTN73431052

Two versus one injection for eye block

Submission date	Recruitment status	[_] Prospectively registered
30/09/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2020	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
Efficacy of Sub-Tenon's block using an equal volume of local anaesthestic administered either as a single or as divided doses

Acronym
SubTenon

Study objectives
Our hypothesis was that a divided injection into the Sub-Tenons space would achieve greater, more consistent and more rapid motor blockade then a single injection using equal volumes and mixtures of local anaesthetic solution.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Cork University Hospital, approval received in 2003.

Study design
Single blinded, prospective, randomised controlled trial

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
Cataract surgery

Interventions
On arrival in the induction room, intravenous excess was secured and monitoring with non-invasive blood pressure (NIBP), electrocardiogram (ECG), and pulse oximetry (Datex AS3) established. Topical anaesthesia was established by instillation of benoximate eye drops and after 2 minutes an eye speculum inserted. With the eye in neutral position, the conjunctiva was lifted in the infranasal quadrant with the help of Moorsfields forceps and using Westcott's scissors a small incision was made in the conjunctiva. A 19 gauge Stephens's cannula was carefully placed subconjuctivally into the Sub-Tenon's space.

In group 1, 5 ml of local anaesthetic solution comprising 2.5 ml of 2% lignocaine with 1:200,000 adrenaline, 15 IU/ml of hyaluronidase and 2.5 ml of 0.5% bupivacaine was injected over thirty seconds. After the injection orbital pressure was applied for two minutes.

In group 2, 3 ml of the same anaesthetic solution described above was injected and cannula withdrawn followed by application of orbital pressure for 2 minutes. A further 2 ml of the same anaesthetic solution was injected through the same conjunctival incision with approx three minutes between the two injections.

Intraocular pressures were measured by a hand held tonometer (knowa) prior to injection and six minutes after the first (or sole) injection and compared with pre-injection value.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Benoximate, lignocaine, adrenaline, hyaluronidase, bupivacaine

Primary outcome measure
Measurement of movement was performed by the operating surgeon who was unaware of the anaesthetic technique used in all four quadrants (inferior, superior, redial, lateral) using a vernier calliper and scored according to movement:
0 = no movement
1 = movement of less than 2 mm
2 = movement of more than 2 mm

Motor function was evaluated at two time intervals, 3 and 6 minutes after the initial injection. Overall movement score was obtained by combining the scores of these four muscles. This score ranged from 0 (no movement) to 8 (complete movement) and was categorised into two groups, akinesia (score 0 - 4) and no akinesia (score 5 - 8).

All measured during the surgery.

Secondary outcome measures
Chemosis and subconjuctival haemorrhage were also assessed by surgeons before starting surgery as mild, moderate or severe. All measured during the surgery.

Overall study start date
01/06/2003

Completion date
31/12/2003

Eligibility

Key inclusion criteria
1. American Society of Anaesthesiologists (ASA) I - III patients undergoing cataract surgery
2. No age range, both male and female patients

Participant type(s)
Patient

Age group
Other

Sex

Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Allergy to any of the drugs administered
2. Impaired mental status
3. Uncontrolled glaucoma
4. Clotting abnormalities
5. Recent surgical procedure on the same eye

Date of first enrolment
01/06/2003

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
Ireland

Study participating centre
South Infirmary Hospital
Cork
Ireland
-

Sponsor information

Organisation
Cork University Hospital (Ireland)

Sponsor details
Wilton
Cork
Ireland
-

Sponsor type
University/education

ROR
https://ror.org/04q107642

Funder(s)

Funder type
Other

Funder Name
Investigator initiated study - no extra funding required as Sub-Tenon's block is routinely used

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	26/03/2009	30/12/2020	Yes	No