

Two versus one injection for eye block

Submission date 30/09/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/10/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/12/2020	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Jawad Mustafa

Contact details

South Infirmary Hospital

Cork

Ireland

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Efficacy of Sub-Tenon's block using an equal volume of local anaesthetic 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 than 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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cataract surgery

Interventions

On arrival in the induction room, intravenous access 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 subconjunctivally 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(s)

Measurement of movement was performed by the operating surgeon who was unaware of the anaesthetic technique used in all four quadrants (inferior, superior, medial, 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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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 Infirmity Hospital

Cork

Ireland

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Sponsor information

Organisation

Cork University Hospital (Ireland)

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

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