ISRCTN51613333 https://doi.org/10.1186/ISRCTN51613333

Sponge anaesthesia versus topical anaesthesia for subconjunctival antibiotics/steroid injections in Phacoemulsification + Implant Surgery Study

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 26/10/2015	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr T Matthews

Contact details
Ophthalmology
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Additional identifiers

Protocol serial number
N0265122364

Study information

Scientific Title

Sponge anaesthesia versus topical anaesthesia for subconjunctival antibiotics/steroid injections in Phacoemulsification + Implant Surgery Study

Study objectives
Does the application of a pre-soaked oxybuprocaine swab on the conjunctiva reduce the pain of subconjunctival antibiotic/steroid injections more than topical oxybuprocaine alone?

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery: Anaesthesia

Interventions
Prospective randomised control study of patients undergoing phacoemulsification and implant under topical anaesthesia at Sandwell and West Birmingham NHS Trust and University Hospital NHS Trust. Informed consent to be obtained from the patient before the operation.

They will be randomised into two groups:
Group 1 will have a pre-soaked oxybuprocaine sponge placed in the inferior conjunctival fornix at the beginning of the procedure.
Group 2 will have a saline soaked sponge.
Both groups having routine topical anaesthesia for cataract surgery. The patient will be advised before the injection of the subconjunctival antibiotic injection. 1 ml of cefuroxime /betamethasone (this is a routine preparation done on the completion of cataract surgery) will be given into the inferior conjunctival fornix.

The pain assessment will be assessed immediately after the operation by the patient and an independent observer. This will be done with the 0-10 visual analogue scale. The surgeon will also fill in a separate form regarding surgical time. We will then analyse the two groups to determine if a pre-soaked sponge of oxybuprocaine gives more pain relief than a pre-soaked sponge with saline. Both arms of the study will receive a normal anaesthetic to reduce pain.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oxybuprocaine

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
16/07/2008

Eligibility

Key inclusion criteria
To enroll 100 patients over 6 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
16/01/2003

Date of final enrolment
16/07/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration