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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 26/10/2015	**Condition category** Surgery	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/01/2003

Completion date
16/07/2008

Eligibility

Key inclusion criteria
To enroll 100 patients over 6 months

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

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
England

United Kingdom

Study participating centre
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

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