

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

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| Submission date 12/09/2003 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 12/09/2003 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 26/10/2015 | Condition category Surgery | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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