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Cryoanalgesia as an adjunct to topical anaesthesia in cataract surgery

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28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/09/2016	Eye Diseases	[ ] Record updated in last year

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
N0274185690

Study information

Scientific Title

Cryoanalgesia as an adjunct to topical anaesthesia in cataract surgery

Study objectives
Does cryoanalgesia i.e. the application of a cold gel eye pack pre-operatively improve patient comfort during cataract surgery performed under topical anaesthesia?

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

Health condition(s) or problem(s) studied
Eye Diseases: Cataract

Interventions
Purpose:
Cryoanalgesia alone can produce satisfactory anaethesia for cataract surgery (phacoemulsification). It does not however supersede topical anaesthesia but could offer additional benefits when used in conjunction with topical anaesthesia. We hypothesize that the application of a cold gel pack to the eye prior to installation of topical anaesthesia will provide the following benefits: Greater patient satisfaction with overall anaesthesia. This may come about because of:
1. Improved comfort during instillation of topical anaesthesia (less stinging)
2. Improved comfort throughout the surgical procedure ie improved lid comfort during speculum insertion and removal of surgical drape.

Improved comfort immediately post operatively
3. Improved visual recovery and reduced inflammation

Design:
Randomised controlled cross over trial. 50 patients: patients enrolled into the study at a

preoperative assessment by doctors and nurses in the day treatment center (DTC). Consecutive patients that had bilateral cataracts, both requiring surgery, were enrolled according to the inclusion and exclusion criteria.

Consent:
Patients were given an information leaflet regarding the trial on the day of the pre-assessment and written informed consent was obtained. Approval from the ethics committee was also requested.

Procedure for cross-over:
The first eye was randomised to one of the two anaesthetic regimes (see below).
The second eye would then receive the other regime when operated on at a later date. Gel packs were removed temporarily to apply mydriatics and to check for the degree of mydriasis. The surgeon is masked as to which regime the patient is receiving. The same surgeon performed the operation on each eye. The pupil was dilated in the usual manner, proxymethacaine, cyclopentolate 1% and phenylephrine 2.5% at 10 minute intervals 30 minutes prior to surgery.

Regime 1:
The first regime was topical anaesthesia alone. A customised gel pack at room temperature was placed over the eye 10 minutes prior to surgery. Patients receive 2 drops of amethocaine and 5% aqueous betadine to the conjunctiva at 5 minutes before entry to the operating theatre. Standard topical anesthesia regime follows as normal: One drop of amethocaine is instilled following speculum insertion, prior to the operation commencing. Intracameral anaesthesia with 0.5%lignocaine in BSS was administered during surgery (hydrodissection).

Regime 2:
The second regime includes topical anaesthesia and cryoanaesthesia. A customised gel pack cooled to 4 degrees Celcius is placed over the eye 10 minutes prior to surgery. Patients receive 2 drops of amethocaine and 5% aqueous betadine to the conjunctiva at 5 minutes before entry to the operating theatre. Standard topical anesthesia regime follows as normal: One drop of amethocaine is instilled following speculum insertion, prior to the operation commencing. Intracameral anaesthesia with 0.5%lignocaine in BSS is administered during surgery (hydrodissection).

Following surgery the operated eye is covered by a clear cartella shield and the patient returns to the day surgery cataract lounge. Once the patient is seated and comfortable a patient satisfaction questionnaire is administered by non medical staff, i.e. patient relative or friend or self. The time to fill in the form is not limited. None of the investigators or operators are in contact with the patient during this time.

Patient satisfaction was measured using the Iowa Satisfaction with Anaesthesia Scale (ISAS), a self-administered written questionnaire, which has been shown to be internally consistent, reliable and a valid measure. Patients respond to 11 statements (see below) by placing a mark along a six choice vertical response column (eg disagree moderately). A totally satisfied patient would score +3, a totally dissatisfied patient would score -3. The mean of their responses to the 11 statements gives a single number between -3 and +3, which is a quantitative measure of a patients satisfaction with their anaesthesia care.

Apart from the demographic data the following variables were recorded when each eye was operated on: duration of application of gel pack if greater or less than 10 minutes, duration of surgery if greater than 20 minutes, complications of anaesthesia or surgery, grade of surgeon, same surgeon (if second eye)

Patients are discharged from the cataract unit with standard topical treatment: Gutt: Maxidex tds and Gutt. Chlorampnenicol qds to the operated eye for 3 weeks. Patients are seen at a post-operative assessment clinic at 4 weeks and the following information recorded:
1. Visual acuity (unaided and pinhole)
2. Activity of anterior chamber ie nil or persistent uveitis
3. Post operative complications eg cystoid macular oedema

Any other patient comments:
The operating surgeon will not assess post operative study patients. Patients are given a date for their second eye operation or discharged if both eyes have been operated upon after 4 weeks.This study does not involve any additional clinic visits or alteration in usual patient care. Patients will be provided (posted) a summary of the study findings if they request so.

References:
1. Agarwal A, Agarwal S, et al. No anesthesia cataract surgery with karate chop. In Phacoemulsification Laser Cataract Surgery and Foldable IOLs. Jaypee Brothers, New Delhi 1998; 19:144-154
2. Gutierrez-Carmona FJ. Phacoemulsification with Cryoanalgesia: A New Approach for Cataract Surgery. In Phacoemulsification, Laser Cataract Surgery and Foldable IOLs. Jaypee Brothers Medical Publishers (2nd ed), New Delhi, 2000; 23:226-229
3. Gutierrez-Carmona FJ, Alvarez-Marin J. Randomized comparative clinical study of cryoanalgesia versus topical anesthesia in clear corneal phacoemulsification.
J Cataract Refract Surg. 2005 Jun;31(6):1187-93.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patient comfort score during procedure as measured by the Iowa Satisfaction with Anaesthesia Scale (ISAS).

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2006

Completion date
01/06/2007

Eligibility

Key inclusion criteria
All those suitable to undergo surgery in the day case setting and undergoing clear corneal incision phacoemulsification under topical anaesthesia.

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Those unable to understand the information about the trial for any reason
2. Complicated cataract cases eg small pupils
3. Patients with previous intraocular surgery eg Retinal detachment, vitrectomy, trabeculectomy
4. Patients with previous intraocular inflammation: Uveitis
5. Diabetics (neuropathy)
6. Patients requiring additional anaesthesia eg. subtenons anaesthesia
7. Patients whose cataract surgery lasts longer than 20 mins

Date of first enrolment
01/12/2006

Date of final enrolment
01/06/2007

Locations

Countries of recruitment
England

United Kingdom

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Sponsor information

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Record Provided by the NHSTCT Register - 2007 Update - Department of Health (UK)

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Funder(s)

Funder type
Government

Funder Name
West Suffolk Hospitals NHS Trust

Funder Name
NHS R&D Support Funding

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