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# Comparison of 4% articaine and bupivacaine /lignocaine for sub-tenon anaesthesia in phacoemulsification cataract surgery

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|---|---|---|
| **Submission date**<br>30/09/2004 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>30/09/2004 | **Overall study status**<br>Completed | |
| **Last Edited**<br>22/02/2008 | **Condition category**<br>Eye Diseases | |

**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**
N0203132063

# Study information

## Scientific Title

## Study objectives
To assess if articaine 4% is a suitable and SAFE agent for use in sub-tenon anaesthesia of the eye (for cataract surgery).

## 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
Cataract surgery

## Interventions
Patients will be randomly allocated to one of two groups using sealed, numbered envelopes and computer randomisation. Group A will receive sub-tenon's anaesthesia using 4% articaine and group B will receive a mixture of equal volume of 0.5% bupivicaine and 2% lignocaine. Ocular movements will be scored for each direction of gaze in the superior, inferior, medial and lateral directions with a maximum score for each direction of 3 points and a possible total maximum of 12 points. Patients will be considered to be ready for surgery when the ocular scores are 5 or less. Table showing scoring system for ocular movements. Full Movement 3/ Moderate Movement 2/ Flicker of movement 1/ No movement 0. In addition formal ocular motility testing will be undertaken at the orthoptics department immediately before and after surgery.

## Intervention Type
Drug

## Phase

Not Specified

### Drug/device/biological/vaccine name(s)
Articaine, bupivacaine/lignocaine

### Primary outcome measure
The aim of the trial is to examine the possibility that the success rate of sub-tenon anaesthesia can be improved by using 4% articaine rather than the presently used combination of lignocaine /bupivacaine. Sub-tenon's anaesthesia has distinct advantages over 'sharp needle' technique, chiefly being globe perforation but currently, acceptance of this technique is hampered by poor success rate. If the success rate of sub-tenons anaesthesia could be enhanced by 4% articaine then it would become a widely used technique.

Study endpoints: Collating data and to see if 4% articaine is safe and effective compared to existing lignocaine/bupivacaine anaesthetic agent.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
16/09/2003

### Completion date
31/12/2005

## Eligibility

### Key inclusion criteria
Patient will be selected at random from the waiting list. Letters will be sent out to the patient along with appointment letter. They will be contacted a day prior to surgery and their willingness to participate ascertained on the day of surgery.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
65

### Key exclusion criteria
1. Aged less than 18 years
2. Previous intra-ocular surgery
3. Pupil diameter less than 5 mm when fully dilated
4. Pregnant females or of child bearing potential
5. Those known to have reduced plasma chlolinesterase levels

6. Patient unwilling to participate in the study
7. A history of allergy to amide-type anaesthetics
8. Subjects of non-therapeutic research

**Date of first enrolment**
16/09/2003

**Date of final enrolment**
31/12/2005

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Royal Devon & Exeter Hospital (Wonford)**
Exeter
United Kingdom
EX2 5DW

# Sponsor information

**Organisation**
Department of Health

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

**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

### Funder type
Government

### Funder Name
Royal Devon and Exeter 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | Results | 01/04/2008 | | Yes | No |