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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
30/09/2004		<pre>Protocol</pre>		
Registration date	Overall study status	Statistical analysis plan		
30/09/2004	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
22/02/2008	Eve Diseases			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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# Additional identifiers

Protocol serial number 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

## Study type(s)

Treatment

## 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(s)

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.

## Key secondary outcome(s))

Not provided at time of registration

## 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

## Healthy volunteers allowed

No

## Age group

Adult

#### Sex

All

## 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

United Kingdom

England

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

# Sponsor information

## Organisation

Department of Health

# Funder(s)

## Funder type

Government

## Funder Name

Royal Devon and Exeter NHS Trust (UK)

# **Results and Publications**

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