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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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