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Trial of Articaine for Peribulbar Anaesthesia

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 20/02/2020	**Condition category** Surgery	[ ] Individual participant data [ ] 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
N0203052841

Study information

Scientific Title

-

Study objectives
Would articaine be suitable, safe and reliable anaesthetic for peribulbar anaesthesia?

Peribulbar anaesthesia is the most commonly employed anaesthetic for cataract surgery. This involves normally two injections of local anaesthetic around the eye to achieve analgesia and akinesia. Each injection carries a risk globe perforation or haemorrhage which can in extreme cases cause blindness. Recently a single injection technique has been described, but failure to achieve akinesia can be as high as 40% due to inadequate diffusion of the local anaesthetic agent.
Articaine is a local anaesthetic used principally in dental practice because of its safety and good diffusion properties.
We propose to trial the use of Articaine for peribulbar anaesthesia to examine if these diffusion properties could be useful in reducing morbidity from peribulbar anaesthesia by reducing the number of injections needed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blinded patient study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Anaesthesia

Interventions
We intend to compare the effectiveness of articaine against the current standard-agent (prilocaine) when used for peribulbar anaesthesia.
Patients attending for cataract surgery, and giving informed consent, will be randomly allocated to receive anaesthesia with one of the two agents. A standard single injection technique of peribulbar anaesthesia will be used. Akinesia will be assessed at one, five and ten minutes, and where necessary a second 'top-up' injection performed at five minutes.
The results will let us compare the effectiveness of Articaine when used for peribulbar

anaesthesia and also demonstrate if the diffusion of Articaine is sufficient to enable reliable anaesthesia when using only a single peribulbar injection.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
articaine prilocaine

Primary outcome measure
Study endpoints: comparison of the degree of anaesthesia and akinesia achieved with Articaine and prilocaine when using a single injection peribulbar technique.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2000

Completion date
31/07/2005

Eligibility

Key inclusion criteria
200 patients age 16 - 100 years (patient population attending for eye surgery tends in practice to be elderly with an expected average age of around 70 years). Patients attending for cataract surgery under local anaesthesia will be invited to join the study. Patients will be sent an information sheet explaining the purpose of the trial with their booking letter. Consent to take part in the trial will then be obtained after discussion with one of the investigators on the day of admission.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
200

Key exclusion criteria
Patients will be excluded if less than 16 years of age, female (if pregnant or of child bearing potential) or known to have reduced plasma cholinesterase levels.

Date of first enrolment
01/01/2000

Date of final enrolment
31/07/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Devon & Exeter Hospital (Wonford)
Exeter
United Kingdom
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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Sponsor type
Government

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

Funder(s)

Funder type
Not defined

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