

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

Protocol serial number

N0203052841

Study information

Scientific Title

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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

Primary study design

Interventional

Study design

Randomised double-blinded patient study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

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
Not defined

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