ISRCTN11415977 https://doi.org/10.1186/ISRCTN11415977

Comparing two local anaesthetic drugs in treatment of children's teeth

Submission date
17/09/2012

Recruitment status
No longer recruiting

Registration date
12/10/2012

Overall study status
Completed

Last Edited
15/10/2020

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Studies have found that the anaesthetic articaine is more effective and has comparable safety to the anaesthetic lidocaine when used as in routine dental treatments on permanent teeth in adults. However, as far as we are aware there no studies have been conducted to compare the effectiveness of articaine to lidocaine during dental treatment of children's primary molar teeth (i.e., milk teeth). Therefore, the aim of this study is to compare the anaesthetic effectiveness of articaine and lidocaine in the dental treatment of primary molars in children aged 5-9. We will also evaluate the response of children when they receive the local anaesthetic injection, in order to recommend the most effective and acceptable method of injection.

Who can participate?
Children aged 5-9 who are attending Leeds Dental Hospital for dental treatment.

What does the study involve?
Participants are randomly allocated into two groups. One group is treated with articaine and the other group is treated with lidocaine. The child's reaction to the injection is assessed by asking them to rate the pain, discomfort and numbness. The acceptability of the treatment is assessed using a questionnaire.

What are the possible benefits and risks of participating?
The participant may not personally benefit but we are hoping to find out which is the most effective treatment for future use. The risks are the same as any other routine dental treatment, including pain, discomfort, strange feeling of numbness, and lip or cheek biting.

Where is the study run from?
Leeds Dental Institute, University of Leeds (UK).

When is the study starting and how long is it expected to run for?
January 2013 to September 2015.

Who is funding the study?
University of Leeds (UK).

Who is the main contact?
Dr Fatma Alzahrani

Contact information

Type(s)
Scientific

Contact name
Prof Monty Duggal

Contact details
Consultant and Head of Paediatric Dentistry
University of Leeds
Child Dental Health
Leeds Dental Institute
Clarendon Way
Leeds
United Kingdom
LS2 9LU

Additional identifiers

Clinical Trials Information System (CTIS)
2011-004711-23

Protocol serial number
DT11/9936

Study information

Scientific Title
Comparative studies of the anaesthetic efficacy of 4% Articaine with 1:100,000 epinephrine used as mandibular infiltration versus 2% Lidocaine with 1:80,000 epinephrine used as inferior dental nerve block, in extraction and restoration of mandibular primary molars

Study objectives
There is no difference in the pain experience between mandibular infiltration using 4% articaine with 1:100,000 epinephrine and the conventional technique inferior alveolar nerve block using 2% lidocaine with 1:80,000 epinephrine in dental treatment of mandibular primary molars.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Parallel prospective randomised control trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dental caries

Interventions
We will randomly assign the subjects into 2 groups; one group (Treatment group) will receive mandibular infiltration with 4% articaine with 1:100,000 and the other group (Control group) will receive inferior alveolar nerve block with 2% lidocaine with 1:80,000.

All local anaesthetic injections will be given by a single operator ,who will assess the child behaviour during the injection procedures (using Frankl Behaviour Scale). Each child will receive one treatment for one tooth only. The assessment will be done during all the procedures.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Articaine, Lidocaine

Primary outcome(s)
Successful completion of treatment

Key secondary outcome(s))
1. Child perception of the treatment using specific questionnaire developed by the researcher
2. Parent perception of the treatment using specific questionnaire developed by the researcher

Completion date
01/09/2015

Eligibility

Key inclusion criteria
1. Children aged 5 to 9 years
2. Medically fit
3. Requiring extraction /restoration of primary mandibular molars teeth under local anaesthetic
4. Understand English
5. Mentally capable of communication
6. Tooth has no history of infection (abscess) or swelling and no evidence of periapical pathosis
7. The roots resorption of the primary tooth must be less than half of the root
8. Parents/guardian must give informed written consent prior to participation
9. Child must give assent form prior to participation, as well as parental consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
9 years

Sex
All

Total final enrolment
98

Key exclusion criteria
1. Medically and mentally compromised children
2. History of significant behaviour management problems
3. Evidence of infection near the proposed injection site as this might affect the efficacy of local anaesthesia
4. Child does not speak English

Date of first enrolment
01/01/2013

Date of final enrolment
01/09/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Leeds
Leeds
United Kingdom
LS2 9LU

Sponsor information

Organisation
University of Leeds (UK)

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
University/education

Funder Name
University of Leeds (UK) ref: DT11/9936

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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	01/05/2018	15/10/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes