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Feasibility and advantages of using more comfortable combined injection technology in the treatment of deciduous molars

Submission date
09/05/2025

Recruitment status
No longer recruiting

Registration date
12/05/2025

Overall study status
Completed

Last Edited
16/07/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
To find a local anesthesia has both comfortable and effective advantage in treatment of deep caries in mandibular deciduous molars in children.

Who can participate?
Children aged 4-6 years old (below 7) have deep caries in mandibular deciduous molars.

What does the study involve?
Two types of local anesthesia before the treatment of deep caries in mandibular deciduous molars: regular periodontal ligament injection and intraseptal injection combined with periodontal ligament injection.

What are the possible benefits and risks of participating?
Possible benefits: children received intraseptal injection combined with periodontal ligament injection have lower pain sensation during anesthesia; possible risks: children received intraseptal injection combined with periodontal ligament injection might still have pain sensation during treatment and need supplementary local anesthesia.

Where is the study run from?
Shenzhen Maternity and Child Healthcare Hospital (China)

When is the study starting and how long is it expected to run for?
May 2022 to June 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Jin Sun, 631589163@qq.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Feasibility and advantages of using intraseptal injection combined with periodontal ligament injection in the treatment of mandibular deciduous molars

Study objectives
The anesthetic effect of intraseptal injection combined with periodontal ligament injection and periodontal ligament injection alone were similar, moreover, intraseptal injection combined with periodontal ligament injection had lower pain sensation during the anesthesia.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 19/05/2022, The Research Ethics Committee of Shenzhen Maternity and Child Healthcare Hospital (Hongli Road, Futian District, Shenzhen, 518000, China; -; szfygcpll@163.com), ref: SFYLS[2022]025

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Deep caries in mandibular deciduous molars

Interventions
Control group: group PL: periodontal ligament injection
Intervention group: group IS+PL: intraseptal injection combined with periodontal ligament injection

The total duration of treatment for deep caries is approximately 0.5-1 hour.

Randomization process: we toss a coin before meeting each child. The front of the coin represents the control group, and the back of the coin represents the intervention group.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain measured using the Wong-Baker FACE® Pain Rating Scale immediately after the anesthesia and immediately after the treatment

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/05/2022

Completion date
01/06/2023

Eligibility

Key inclusion criteria
1. Parents agreed to the experiment.
2. Children aged 4-6 years old (below 7).
3. Can communicate with pediatric dentist or nurse normally.
4. Had eaten food within 2 hours before treatment.
5. Mandibular deciduous molars erupted completely.
6. Had deep caries.
7. No obvious spontaneous, night, or occlusal pain or periapical periodontitis symptoms.
8. X-ray showed low density shadow close to pulp.
9. No obvious low density shadow at root tip.

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Parents refused the experiment.
2. Children were unable to cooperate.
3. Did not eat within 2 hours before treatment.
4. Had temporary or long-term systemic disease.
5. Allergic to anesthetics.
6. Oral mucosal diseases.
7. Wearing orthodontic appliances.
8. Mandibular deciduous molar did not erupt completely.
9. No deep caries.
10. Had obvious spontaneous, night, or occlusal pain or periapical periodontitis symptoms.
11. X-ray showed low density shadow at root tip or already had root canal therapy.

Date of first enrolment
01/06/2022

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
China

Study participating centre
Shenzhen Maternity and Child Healthcare Hospital
Hongli Road, Futian District
Shenzhen
China
518000

Sponsor information

Organisation
Shenzhen Maternity and Child Healthcare Hospital

Sponsor details
Hongli Road, Futian District
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szfygcpll@163.com

Sponsor type
Hospital/treatment centre

Website
http://www.szmch.net.cn/

ROR
https://ror.org/01me2d674

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/01/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Jin Sun 631589163@qq.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/07/2025	16/07/2025	Yes	No