

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

<b>Submission date</b> 09/05/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/05/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/07/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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

## Contact name

Mr Jin Sun

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

There are no secondary outcome measures

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

4 years

**Upper age limit**

6 years

**Sex**

All

**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

## ROR

<https://ror.org/01me2d674>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## 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?
<a href="#">Results article</a>		03/07/2025	16/07/2025	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes