

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of oral analgesic on patient's reaction during pulpal exposure in children 5 to 8 years old a randomized clinical trial.

Protocol summary

Study aim

Determining the effect of oral analgesic on the patient's reaction during pulp exposure of primary teeth in five to eight yearold children.

Design

A randomized cross over thriple blind clinical trial of 40 patients. <https://www.randomizer.org> is used for randomization.

Settings and conduct

40 of the pediatric patients of the pediatric department of Mashhad dental school, in need of pulpal treatment for Both of the primary maxillary first molars are selected. In first visit placebo or medical treatment intervention (chosen based on block randomized charts in closed envelopes), is given one hour prior to the start of dental treatment. In the next visit after a wash-out period of one week, the alternative is given in the same manner. The operators follow the same treatment protocol and are calibrated together. The child's reaction at the moment of pulpal exposure is measured using FLACC in the groups and subgroups of the study. The FLACC score is a valid and reliable pain assessment tool for children.

Participants/Inclusion and exclusion criteria

Children aged 5 to 8 years who require pulpal treatment of maxillary D teeth, with informed parental consent.

Intervention groups

Intervention group 1: Acetaminophen syrup is given to the child one hour before the dental treatment on the first session and on the second session multivitamin syrup is given similarly. intervention group 2: multivitamin syrup is given to the child one hour before the dental treatment on the first session and on the second session acetaminophen syrup is given similarly.

Main outcome variables

pain level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230125057218N2**

Registration date: **2023-12-11, 1402/09/20**

Registration timing: **prospective**

Last update: **2023-12-11, 1402/09/20**

Update count: **0**

Registration date

2023-12-11, 1402/09/20

Registrant information

Name

Rasoul Sahebalam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 9501

Email address

sahebalamr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-05, 1402/10/15

Expected recruitment end date

2024-04-03, 1403/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral analgesic on patient's reaction during pulpal exposure in children 5 to 8 years old a randomized clinical trial.

Public title

Effect of analgesics during pulp therapy of deciduous teeth.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients in need of bilateral pulp treatment of the first primary molar tooth of the upper jaw.

Exclusion criteria:

Patients requiring antibiotic prophylaxis for dental treatments. Patients with cooperation problems.

Age

From **5 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

First primary molar on the both sides of maxilla.

Randomization (investigator's opinion)

Randomized

Randomization description

In this study permuted block technique randomizes patients between groups within a set of study participants, called a block. For this purpose, random allocation sequence of people will be used using Random Allocation Software and block size of two. In this study there are two blocks of AB and BA. A represents placebo and B represents Acetaminophen syrup. One of these blocks is selected randomly and people will be allocated to AB or BA blocks accordingly. This process will be continued until all of the samples have been allocated.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participant is unaware which of the medical intervention or placebo they used due to the similarity of the shape of the bottles and the taste of medical intervention and placebo. Evaluator is unaware whether the drug or placebo used by denoting similar bottles in A and B (A and B are written on the bottom of the bottles). Data analyst becomes unaware which data belongs to each of the groups through coded group names (A and B).

Placebo

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Vakil Abad Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2023-03-13, 1401/12/22

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1401.158

Health conditions studied**1****Description of health condition studied**

The degree of discomfort or pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Discomfort and pain

Timepoint

during pulpal exposure

Method of measurement

Behavioral assessment scale FLACC(Face, Legs, Activity, Cry, Consolability scale)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Behsa's corp. Acetaminophen syrup (120mg acetaminophen per 5cc) with the dose of 15mg acetaminophen per 1kg is given to the child one hour before the dental treatment on the first session and on the second session Shahredar's corp. Mester Vit multivitamin syrup is given in the same amount as acetaminophen one hour before the dental treatment.

Category

Prevention

2**Description**

intervention group 2: Shahredaru's corp. Mester Vit multivitamin syrup is given in the same amount as acetaminophen one hour before the dental treatment on the first session and on the second sessionBehsa's corp. Acetaminophen syrup (120mg acetaminophen per 5cc) with the dose of 15mg acetaminophen per 1kg is given to the child one hour before the dental treatment.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mashhad Faculty of Dentistry

Full name of responsible person

Rasoul sahebalam

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Mashhad Faculty of Dentistry, Vakilabad Blvd.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology of
Mashhad University of Medical Sciences

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Rasoul Sahebalam

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Department of Pediatric Dentistry, Faculty of
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Rasoul sahebalam

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The details of the participants, such as age, sex, and the teeth studied, will be published by hiding their identities.

When the data will become available and for how long

Access to information will be from 2025 onwards.

To whom data/document is available

Researchers working in academic and scientific institutions who require this information can have access to it.

Under which criteria data/document could be used

Is allowed with citation.

From where data/document is obtainable

They can refer to Mashhad dental school's library or Mashhad University of Medical Sciences library website.

What processes are involved for a request to access data/document

Information will be available in thesis format.

Comments