Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 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 fisrt 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)

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+98 51 3882 9501

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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 Shahredaru'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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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 Dentistry, Vakil Abad Blvd.
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Person responsible for scientific inquiries

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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