

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of premedication with Acetaminophen and Ibuprofen on post-operative pain after pulpectomy in primary mandibular molar teeth with irreversible pulpitis

Protocol summary

Study aim

Efficacy of premedication with Acetaminophen and Ibuprofen on postoperative pain after pulpectomy in primary mandibular molar teeth with irreversible pulpitis

Design

Nonrandomized, double-blinded, phase 3 clinical trial with a control group with a group design of 78 patients

Settings and conduct

In this double-blinded study, participants and the Principal Investigator will be kept blind. After preparing the initial graphy with the parallel method, The teeth will be pulpectomized, the roots will be filled with ZOE paste, and then the teeth will be repaired with SSC. A second-year resident will perform the whole treatment process in the pediatric ward of Ahvaz Jundishapur University School of Dentistry. After treatment, the patient's parents will be asked to complete the Wong-baker faces pain rating scale test by asking about the child's pain. Pain intensity will be assessed up to h24 and h48 after treatment.

Participants/Inclusion and exclusion criteria

Entry requirements for participants: History of spontaneous pain; Teeth with internal resorption that involve 1/3 of the root; Teeth with external resorption(not physiological) less than 1/3 of the root length; Conditions for non-entry of participants: Unrestorable crown; Furca radiolucency that involves permanent tooth bud; External resorption more than 1/3 of the root length; Pulp canal obstruction; Existence of systemic disease; two visit pulpectomy

Intervention groups

In the control group, a strawberry-flavored suspension is given to the patient 45 minutes before work. In the second intervention group, 10-15 mg/kg acetaminophen syrup is given to the patient forty-five minutes before work. In the third intervention group, ibuprofen suspension 4-10 mg/kg, is given forty-five minutes

before work.

Main outcome variables

Measuring the pain after treatment based on Wong-baker faces pain rating scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200617047820N1**

Registration date: **2020-11-16, 1399/08/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-16, 1399/08/26**

Update count: **0**

Registration date

2020-11-16, 1399/08/26

Registrant information

Name

Bahare Tahmasbi karfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2207 1959

Email address

tahmasbibahare@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-28, 1399/07/07

Expected recruitment end date

2020-12-27, 1399/10/07

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of premedication with Acetaminophen and Ibuprofen on post-operative pain after pulpectomy in primary mandibular molar teeth with irreversible pulpitis

Public title
Effect of Acetaminophen and Ibuprofen on post-operative pain after treatment of primary teeth

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Teeth that have a history of spontaneous pain Teeth with internal resorption that involves 1/3 of cervical root. Teeth with external resorption (not physiological resorption) that involves less than 1/3 of root length
Exclusion criteria:
 Unrestorable crown Furcate radiolucency which involves permanent tooth bud External resorption more than 1/3 of the root length Pulp canal obstruction Two visit pulpectomy

Age
From **6 years** old to **10 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the principal investigator and the participants will be kept blind, and They do not know which drug the doctor puts in the group. Data collection authorities and those evaluating the outcome and the doctor are aware of the nature of the drug in the relevant group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2020-08-22, 1399/06/01

Ethics committee reference number

IR.AJUMS.REC.1399.419

Health conditions studied

1

Description of health condition studied

Efficacy of premedication with Acetaminophen and Ibuprofen on post-operative pain after pulpectomy in primary mandibular molar teeth with irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Pain is measured based on Wong-baker faces pain rating scale.

Timepoint

Measuring the child's pain 24 and 48 hours after treatment

Method of measurement

Wong-baker faces pain rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: They will receive a placebo that contains a strawberry-flavored suspension. The placebo will be given to the patient 45 minutes before work.

Category

Treatment - Drugs

2

Description

Intervention group: In this group, the patient will be given acetaminophen syrup 15-10 mg / kg forty-five minutes before work.

Category

Treatment - Drugs

3

Description

Intervention group: In this group, ibuprofen suspension 4-10 mg / kg will be given to the patient forty-five minutes before work.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Parisa Jafarnejadi

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Ahvaz Jundishapur University of Medical Sciences,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr .Mohammad Badvi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Bahare Tahmasbi Karfi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Position

Assistant professor

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Specialist

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Dentistry

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Person responsible for updating data

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Name of organization / entity

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available