Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A split-mouth randomized controlled trial: Comparative study of pre-medication with paracetamol, Ibuprofen and placebo on post operative pain following pulpotomy in 6-12 years old children

Protocol summary

Study aim
Comparison of pre-medication with paracetamol, Ibuprofen and placebo on post operative pain following pulpotomy in 6-12 years old children

Design
A single-blind, randomized clinical trial on 27 patients, each of whom received all interventions. SAS software was used for randomization.

Settings and conduct
In this study, 27 children aged 6-12 years old referred to the specialized clinic of Rasht Faculty of Dentistry, in need of pulpotomy of at least 3 primary molar teeth in the lower jaw, and 45 minutes before the start of the work, randomly, once with ibuprofen 100 mg/5ml We pre-treat once with paracetamol 120 mg/5 ml and once with placebo (in this way, each child will definitely receive all three drugs). In this study, children do not know about the syrup they consume.

Participants/Inclusion and exclusion criteria
Patients' be 6-12 years old; not accessing hemostasis during pulp treatment; not accessing adequate anasthesia

Intervention groups
Comparison of pre-medication with paracetamol, Ibuprofen and placebo on post operative pain following pulpotomy

Main outcome variables
Pain after pulpotomy treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221011056145N1**
Registration date: **2022-10-30, 1401/08/08**
Registration timing: **registered_while_recruiting**
Last update: **2022-10-30, 1401/08/08**
Update count: **0**

Registration date
2022-10-30, 1401/08/08

Registrant information

Name
Hediyeh Daneshvar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 8433 6046

Email address
dr.daneshvar@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-21, 1401/07/29

Expected recruitment end date
2022-11-21, 1401/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A split-mouth randomized controlled trial: Comparative study of pre-medication with paracetamol, Ibuprofen and placebo on post operative pain following pulpotomy in 6-12 years old children

Public title
Comparative study of pre-medication with paracetamol, Ibuprofen and placebo on post operative pain following

pulpotomy in 6-12 years old children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The children be 6-12 years old Each patient must have at least 3 teeth for Pulpotomy and SSC in lower jaw Parents' consent to perform the treatment

Exclusion criteria:

Not reaching hemostasis Not reaching adequate anesthesia Any kind of systemic disease that is in contrast to conservative pulp treatment Any radiographic findings including:internal and external resorption, PDL Widening,furcation and periapical radiolucency,root canal calcification Patients with any history of allergy to analgesics or any drugs used in the study Patients are not reachable through phone call Patients with Gastrointestinal problems, Favism, GERD,Active asthma Patients with prolonged bleeding history Presence of abscess or sinus tract

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **27**

More than 1 sample in each individual

Number of samples in each individual: **3**

Tooth in need of pulpotomy

Randomization (investigator's opinion)

Randomized

Randomization description

A random block of 3 was used for randomization.For this reason, based on the following randomization list, patients will receive the following treatments in the order of entering the study.Group A paracetamol, group B ibuprofen and group C placebo.In the same way, in the second measurement based on random selection using a coin, the group receiving paracetamol will receive placebo;The group receiving ibuprofen received paracetamol and the group receiving placebo received ibuprofen.In the last round, any treatment group that did not receive it will receive it. Randomization was done with SAS software version 9.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants of this study have no information of their consuming syrup. The therapist has no knowledge of the syrup consumed by the patients. The statistics analyst does not know about the syrup consumed by the patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of gilan university of medical Sciences

Street address

Gilan Province, Fouman - Saravan Rd, Guilan Academic Complex of Medical Sciences

City

Rasht

Province

Guilan

Postal code

41941 73774

Approval date

2022-04-20, 1401/01/31

Ethics committee reference number

IR.GUMS.REC.1401.035

Health conditions studied

1

Description of health condition studied

Pulpotomy

ICD-10 code

K04.0

ICD-10 code description

Inflammation of the dental pulp, usually due to bacterial infection in dental caries, tooth fracture, or other conditions causing exposure of the pulp to bacterial invasion. Chemical irritants, thermal factors, hyperemic changes, and other factors may als

Primary outcomes

1

Description

Examining the type of drug on pain after pulpotomy treatment

Timepoint

The treatments are done with an interval of one week, and the child is asked to paint the face that is most similar to his feeling about the treated tooth in the intervals of 24, 48, 72 hours after the treatment.

Method of measurement

comparative investigation of pre-treatment with paracetamol, ibuprofen and placebo on pain after pulpotomy treatment in children 6-12 years old" the way of measuring the outcome variable is "Wong-Baker

scale".

2

Description
Examining the age variable on pain after treatment
Timepoint
In the initial treatment session, the age is asked and recorded for each child.
Method of measurement
In the initial treatment session, the age is asked and recorded for each child.

3

Description
Examining the gender variable on pain after treatment
Timepoint
In the initial treatment session, the gender of the child is asked and noted.
Method of measurement
In the initial treatment session, the gender of the child is asked and noted.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Ibuprofen. Ibuprofen suspension 100 mg/5 ml (Iran, Tehran, Hakim) is given 45 minutes before treatment based on the weight of each child.
Category
Treatment - Drugs

2

Description
Intervention group: Paracetamol. Paracetamol syrup 120 mg/5 ml (Tehran, Iran, Korizan) is given 45 minutes before treatment based on the weight of each child.
Category
Treatment - Drugs

3

Description
placebo suspension is given to children 45 minutes before treatment.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasht Faculty of Dentistry Specialized Clinic
Full name of responsible person
Hedyeh Daneshvar
Street address
Imam Khomeini Street - in front of Pardis Hotel - Gilan Special Dental Clinic
City
Rasht
Province
Guilan
Postal code
4188794755
Phone
+98 13 3348 6406
Email
dr.daneshvar@gums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
Street address
In front of 17 Shahrivar Hospital. Shahid Siyadati St., Namjo St.
City
Rasht
Province
Guilan
Postal code
4194173774
Phone
+98 13 3333 5821
Email
research@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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

Rasht University of Medical Sciences
Full name of responsible person
Seyedeh Hedyeh Daneshvar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Complex of Gilan University of Medical Sciences.,Saravan beltway to Foman
City
Rasht
Province
Guilan
Postal code
73774 41941
Phone
+98 13 3348 6406
Email
dr.daneshvar@gums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
seyedeh Hedyeh Daneshvar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Complex of Gilan University of Medical Sciences.,Saravan beltway to Foman
City
Rasht
Province
Guilan
Postal code
4194173774
Phone
+98 13 3348 6406
Email
dr.daneshvar@gums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mahshid Rezadoust
Position
dentistery student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Complex of Gilan University of Medical Sciences.,Saravan beltway to Foman
City
Rasht
Province
Guilan
Postal code
4194173774
Phone
+98 13 3348 6406
Email
mahshid.rezadoust@gmail.com

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
No - There is not 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
Only part of the data is shared, such as information on pain reduction after pulpotomy
When the data will become available and for how long
After printing the results
To whom data/document is available
Dentists, pediatricians, researchers working in academic and scientific institutions
Under which criteria data/document could be used
Using pre-treatments such as ibuprofen, paracetamol and placebo to reduce pain after pulpotomy.
From where data/document is obtainable
Gilan University of Medical Sciences Library
What processes are involved for a request to access data/document
Refer to the website of the library of Gilan Faculty of Dentistry and search in defended theses and approved research projects from 2021 onwards.
Comments