

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Study of the effect of commonly used analgesics on response of teeth with symptomatic, irreversible pulpitis to pulp vitality tests

Protocol summary

Study aim

Evaluation of the effect of common analgesics on dental pulp vitality tests

Design

A randomized, blinded, controlled clinical trial with a parallel group design of 41 patients with symptomatic irreversible pulpitis

Settings and conduct

This study was carried out on patients with diagnosis of symptomatic irreversible pulpitis in dentistry School of Tehran University of Medical Sciences. Cold test and electric pulp test were performed on the tooth with irreversible pulpitis and a sound tooth. Then, either 400 mg Gelofen, 500 mg acetaminophen or placebo was prescribed for the patients. The medications were packed in quit similar packing in order to unawareness(making blind) of the examiner. Vitality tests were then performed on the same teeth at 20, 40 and 60 min after medication intake. Sensitivity to cold test was quantified using a visual analog scale (VAS).

Participants/Inclusion and exclusion criteria

The inclusion criteria : age between 18 to 65 years, systemic health, emergency admission due to symptomatic irreversible pulpitis with moderate to severe pain and prolonged pain response to cold test, and no history of analgesic intake or use of nervous system depressants during the past 6 h. The exclusion criteria : contraindications for taking acetaminophen and/or Gelofen, tooth did not response to cold test, and those who had dental pain originated from periapical tissues.

Intervention groups

Intervention Group 1: was prescribed 400 mg Gelofen
Intervention Group 2: was prescribed 500 mg acetaminophen
Control Group : was prescribed placebo

Main outcome variables

- The pulp response to cold test in teeth with symptomatic irreversible pulpitis and sound teeth in Visual Analogue Scale - The pulp response of teeth with

symptomatic irreversible pulpitis and sound teeth to Electric Pulp Tester Both : at the onset of study and at 20, 40 and 60 minutes after medication intake

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200322046836N1**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **retrospective**

Last update: **2020-05-04, 1399/02/15**

Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

Fatemeh Dibaji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5585 1149

Email address

f-dibaji@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2019-09-23, 1398/07/01
Trial completion date
 2019-10-02, 1398/07/10

Scientific title
 Study of the effect of commonly used analgesics on response of teeth with symptomatic, irreversible pulpitis to pulp vitality tests

Public title
 Effect of commonly used analgesics on response of teeth with symptomatic, irreversible pulpitis to pulp vitality tests

Purpose
 Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
 age between 18 to 65 years, systemic health, emergency admission due to symptomatic irreversible pulpitis with moderate to severe pain and prolonged pain response to cold test, and no history of analgesic intake or use of nervous system depressants during the past 6 h.
Exclusion criteria:
 contraindication for taking acetaminophen and/or Gelofen, patients whose tooth did not response to cold test, and those who had dental pain originated from periapical tissues.

Age
 From **18 years** old to **65 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Care provider

Sample size
 Target sample size: **54**
 Actual sample size reached: **41**

Randomization (investigator's opinion)
 Not randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description
 medications (both real tablets and placebo) were in quite similar packing , so that the examiner was unaware of the type of the medicine in the each packing.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1
Ethics committee
Name of ethics committee
 Ethics committee of Tehran University of Medical Sciences
Street address
 6th floor,Central building of Tehran University of Medical Sciences, Qods str., Keshavarz Blvd., Tehran
City
 Tehran
Province
 Tehran
Postal code
 ۱۴۱۷۴۱۴۴۱۸
Approval date
 2016-08-10, 1395/05/20
Ethics committee reference number
 IR.TUMS.DENTISTRY.REC.1396.4724

Health conditions studied

1
Description of health condition studied
 Symptomatic irreversible pulpitis
ICD-10 code
 K04. 02
ICD-10 code description
 Irreversible pulpitis

Primary outcomes

1
Description
 the pulp response to cold test in teeth with symptomatic irreversible pulpitis and sound teeth in Visual Analogue Scale
Timepoint
 at the onset of study and at 20, 40 and 60 minutes after medication intake
Method of measurement
 The values are based on Visual Analogue Scale and in millimeters

2
Description
 the pulp response of teeth with symptomatic irreversible pulpitis and sound teeth to EPT
Timepoint
 at the onset of study and at 20, 40 and 60 minutes after medication intake
Method of measurement
 The degree displayed by the electric pulp tester when the patients felt pain, burning sensation or heat.

Secondary outcomes
 empty

Intervention groups

1

Description

Intervention group: a single dosage of 400 mg Gelofen (Dana,Tehran,Iran) was prescribed and then dental vitality tests were carried out at 20, 40 and 60 minute later.

Category

Diagnosis

2

Description

Intervention group: 500 mg acetaminophen was prescribed(Kharazmi, Tehran, Iran) and then dental vitality tests were carried out at 20, 40 and 60 minute later.

Category

Diagnosis

3

Description

Control group: a single dosage of placebo tablet was prescribed and then dental vitality tests were carried out at 20, 40 and 60 minute later.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Sooratgar-Aidin

Street address

Tehran University of Medical Sciences, International Campus, School of Dentistry Mahan St. Zam Zam St. Navab Highway, Tehran, Iran, P.O. code: 1894787545

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran university of medical science, International campus

Full name of responsible person

Reza Yazdani

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Tehran University of Medical Sciences, International Campus, School of Dentistry Mahan St. Zam Zam St. Navab Highway, Tehran, Iran

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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

Tehran university of medical science, International campus

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

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Dibaji

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Aidin Sooratgar
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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