Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 21 5585 1149

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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
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Sponsors / Funding sources

1

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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
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Fatemeh Dibaji
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Assistant professor
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