

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1894787545

##### Phone

+98 21 5585 1149

##### Fax

+98 21 5585 1141

##### Email

a-sooratgar@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran university of medical science, International campus

##### Full name of responsible person

Reza Yazdani

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1894787545

##### Phone

+98 21 5585 1149

##### Email

f-dibaji@tums.ac.ir

#### 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

##### 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

##### City

Tehran

##### Province

Tehran

**Postal code**  
1894787545  
**Phone**  
0982155851149  
**Email**  
f-dibaji@tums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Aidin Sooratgar  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Tehran University of Medical Sciences, International Campus, School of Dentistry Mahan St. Zam Zam St. Navab Highway, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1894787545  
**Phone**  
+98 21 5585 1149  
**Fax**  
**Email**  
a-sooratgar@sina.tums.ac.ir

## Person responsible for updating data

### 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  
**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  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1894787545  
**Phone**  
0982155851149  
**Email**  
f-dibaji@tums.ac.ir

## 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