

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Gutta-percha and Mineral Trioxide Aggregate on Post Endodontic Pain in Teeth with Asymptomatic Apical Periodontitis: A Randomized Clinical Trial

#### Protocol summary

##### Study aim

The aim of the present study is to determine post endodontic pain score after root canal therapy using gutta-percha alone or Mineral Trioxide Aggregate plug with gutta-percha in teeth with asymptomatic apical periodontitis.

##### Design

A randomized clinical trial with control group, parallel groups, single-blinded.

##### Settings and conduct

This study will be done in the Faculty of Dentistry Islamic Azad University of Isfahan(Khorasgan). Among patients who enter for root canal therapy, the ones that have asymptomatic apical periodontitis will be chosen. If they sign the informed consent form they will enter the study. Participants are divided into two groups using simple randomization and random number table. Endodontic treatment is similar for both groups except that in one group canal is filled with gutta-percha and the other group, the canal is filled with MTA and gutta-percha. For blinding, a pair of opaque glasses will be worn on the participants' eyes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18 to 65 years old with asymptomatic apical periodontitis teeth. Exclusion criteria: Usage of pain killer during the last 12 hours

##### Intervention groups

Patients who need root canal therapy will be divided into two groups. Root canal therapy will be done with gutta-percha for one group and Mineral Trioxide Aggregate plug and gutta-percha for the other group.

##### Main outcome variables

Post endodontic pain score will be measured in 6, 12, 24, 48, and 72 hours after intervention for each group. Post endodontic pain scores will be compared between two groups at the same time intervals after an intervention.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191104045331N1**

Registration date: **2020-10-27, 1399/08/06**

Registration timing: **retrospective**

Last update: **2020-10-27, 1399/08/06**

Update count: **0**

##### Registration date

2020-10-27, 1399/08/06

##### Registrant information

##### Name

sahel kamgar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2256 8406

##### Email address

sahelkamkar93@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-21, 1397/02/31

##### Expected recruitment end date

2019-01-19, 1397/10/29

##### Actual recruitment start date

2018-05-20, 1397/02/30

##### Actual recruitment end date

2019-04-08, 1398/01/19

##### Trial completion date

2019-06-13, 1398/03/23

## Scientific title

Effect of Gutta-percha and Mineral Trioxide Aggregate on Post Endodontic Pain in Teeth with Asymptomatic Apical Periodontitis: A Randomized Clinical Trial

## Public title

The effect of obturation materials on post endodontic pain

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Ability to read and to understand the questionnaire  
Singnature of the informed consent form  
Patients between 18 to 65 years old  
Tooth with asymptomatic apical periodontitis confirmed with cold test and radiography  
Restorable tooth  
Periapical index of 3, 4 or 5

### Exclusion criteria:

Presence of a sinus tract  
Mandibular second premolar  
Retreatment cases  
Usage of pain killer during the last 12 hours  
Tooth with no occlusal contact

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **60**

Actual sample size reached: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, participants will be divided into two groups using a permuted block randomization method. Randomization will be done using 25 blocks with a 4-factor design. In each factor of the block design two participants are assigned to the control group and two participants to the intervention group. Then 25 numbers, from 1 to 6 will be selected using randomization table. For allocation concealment, the type of groups will be given to participants according to the block order via opaque envelopes by a person who is not aware of the randomization procedure. The canals of the teeth will be filled with gutta-percha in the control group and MTA with gutta-percha in the intervention group.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Using a pair of opaque glasses on participants' eyes during treatment so that the patients won't be able to see the treatment procedure.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Islamic Azad University Isfahan (Khorasgan) Branch

##### Street address

Islamic Azad University of Isfahan (Khorasgan) Branch, Isfahan, East Jey street, Arghavaniye, Daneshgah Boulevard

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8155139998

#### Approval date

2019-07-03, 1398/04/12

#### Ethics committee reference number

IR.IAU.KHUISF.REC.1398.075

## Health conditions studied

### 1

#### Description of health condition studied

Asymptomatic apical periodontitis

#### ICD-10 code

K04.5

#### ICD-10 code description

Chronic apical periodontitis

## Primary outcomes

### 1

#### Description

Score of pain in the questionnaire

#### Timepoint

6, 12, 24, 48 and 72 hours after intervention

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: For teeth with asymptomatic apical periodontitis, after cleaning and shaping, root canal therapy will be done with a thickness of three to five millimeters of ProRoot Mineral Trioxide Aggregate

(Dentsply) plug. The rest of the canal will be filled with gutta-percha (Meta Biomed).

**Category**

Treatment - Other

**2****Description**

Control group: For teeth with asymptomatic apical periodontitis ,after cleaning and shaping, root canal therapy will be done with gutta-percha (Meta Biomed).

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Faculty of Dentistry Islamic Azad University of Isfahan (Khorasgan) Branch

**Full name of responsible person**

Sahel Kamgar

**Street address**

Isfahan, East Jey street, Arghavaniye, Daneshgah Boulevard

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr Masoud Khabiri

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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**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Sahel Kamgar

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Abbasali Khademi Mooghari

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Masoud Khabiri

**Position**

Assistant professor

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Specialist

**Other areas of specialty/work**

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## 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**

Not applicable

**Data Dictionary**

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

**Title and more details about the data/document**

Participants data (pain score, sex and involving jaw without names of participants), study protocol, statistical analysis plan, informed consent form and study report will be shared.

**When the data will become available and for how long**

Documents and data files will be available after publishing the article and will always be available.

**To whom data/document is available**

People working in academy institutions

**Under which criteria data/document could be used**

Educational and research uses

**From where data/document is obtainable**

From the library of Faculty of Dentistry Islamic Azad University of Isfahan (Khorasgan).

**What processes are involved for a request to access data/document**

A formal request should be given to the library of Faculty of Dentistry Islamic Azad University of Isfahan (Khorasgan) and the data will be given to them.

**Comments**

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