Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Isfehan(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

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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 questionaire Singniture 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 Azas Univesity of Isfehan (khurasgan) Branch, Isfehan, East Jey street, Arghavaniye, Daneshgah Boulevard

City
Isfehan

Province
Isfehan

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 Isfehan (Khorasgan) Branch

Full name of responsible person

Sahel Kamgar

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Isfehan, 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
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Latest degree
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Dentistry

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Person responsible for updating data

Contact

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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 Isfehan (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 Isfehan (Khorasgan) and the data will be given to them.

Comments
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