

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Clinical trial t compare the effect of CEM, MTA and Biodentin on dental pulp's histological response in orthodontic patients undergoing tooth extraction.

Protocol summary

Summary

The main goal of the study is to compare the histological response of the pulp to three pulp coating materials: Mineral trioxide aggregate (MTA) , Calcium enriched mixture (CEM) and Biodentin. The design of this study was experimental, randomized, single-blind, control group, placebo-free and single-centered. Inclusion criteria: human premolars; no fillings; cervical erosion; caries; teeth that are going to be extracted for orthodontic treatment; both gender; 14 - 25 years of age. Exclusion criteria: previous caries; filling; history of trauma; periodontal disease; severe pain; need to early extraction; unwillingness to cooperate. Intervention: All teeth in the patients who are included in the study are randomly assigned to drawn number between 1 to 4, then divided by the number they assigned to the following groups: group1: Treatment by MTA; group 2: Treatment by CEM; group 3: Treatment by Biodentin; group 4: Control group. The pulp of the teeth will be exposed and then the substance will be placed on the pulp according to the teeth group and then restoration will be done using RMGI. There will be no process on the control group. Then teeth will be extracted after 6 weeks and will be cut for pathological tests. Primary outcomes: necrosis, dentin formation, odontoblast formation, pulp inflammation type, inflammation intensity and pulp inflammation extension.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091728804N2**
Registration date: **2017-11-18, 1396/08/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-18, 1396/08/27

Registrant information

Name

Razieh Hosseinifar

Name of organization / entity

Dental School, Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2017-10-22, 1396/07/30

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial t compare the effect of CEM, MTA and Biodentin on dental pulp's histological response in orthodontic patients undergoing tooth extraction.

Public title

Dental pulp histological respond to MTA, CEM and

BIODENTIN

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: human premolars; no fillings; cervical erosion; caries; teeth that are going to be extracted for orthodontic treatment; both gender; 14 - 25 years of age.

Exclusion criteria: previous caries; filling; history of trauma; periodontal disease; severe pain; need to early extraction; unwillingness to cooperate.

Age

From **14 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

All teeth in the patients who are included in the study are randomly assigned to drawn number between 1 to 4, then divided by the number they assigned to the following groups: Number 1: Treatment by MTA; Number 2: Treatment by CEM; Number 3: Treatment by BIODENTIN; Number 4: Control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Ebn Sina st. Jahad blvd. Somayed cross section.

City

Kerman

Postal code

Approval date

2017-09-17, 1396/06/26

Ethics committee reference number

IR.KMU.REC.1395.549

Health conditions studied

1

Description of health condition studied

Pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Inflammation type

Timepoint

6 weeks after intervention

Method of measurement

Measurement on pathology slide.

2

Description

Formation of odontoblast cell

Timepoint

6 weeks after intervention

Method of measurement

Measurement on pathology slide.

3

Description

Width of dentin bridge

Timepoint

6 weeks after intervention

Method of measurement

Measurement on pathology slide.

4

Description

Forming dentin bridge

Timepoint

6 weeks after intervention

Method of measurement

Measurement on pathology slide.

5

Description

Necrosis

Timepoint

6 weeks after intervention

Method of measurement

Measurement on pathology slide.

6

Description

Severity of inflammation

Timepoint

6 weeks after intervention

Method of measurement

Measurement on pathology slide.

7

Description

Extent of inflammation

Timepoint

6 weeks after intervention

Method of measurement

Measurement on pathology slide.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Placing Biodontin (Septodont Inc.) on prepared cavity near the pulp of premolar teeth according to manufacturer recommended procedure.

Category

Treatment - Other

2

Description

Intervention group 2: Placing MTA (Angelus Inc.) on prepared cavity near the pulp of premolar teeth according to manufacturer recommended procedure.

Category

Treatment - Other

3

Description

Intervention group 3: Placing CEM (Yektazist dandan Inc.) on prepared cavity near the pulp of premolar teeth according to manufacturer recommended procedure.

Category

Treatment - Other

4

Description

Control group: no procedure is going to be done.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontics Division of Kerman Dentistry University.

Full name of responsible person

Dr. Freshteh Safarian.

Street address

Shafa St.

City

Kerman.

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Kerman University of Medical Sciences

Full name of responsible person

Samaneh Rafiee.

Street address

Kosar blvd.

City

Kerman

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Operative dentistry division of Kerman Dentistry University.

Full name of responsible person

Elina Rahminian.

Position

Resident of operative dentistry of kerman dentistry university.

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty