Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical, radiological and histological evaluation of Pro root-MTA, Biodentine and Theracal in partial pulpotomy of human dental healthy pulp.

Protocol summary

Summary

The main purpose during this study is evaluation of Pro root-MTA, Biodentine and Theracal in partial pulpotomy of human dental healthy pulp. Design of this study is single blind. Thirty intact maxillary and mandibular third molars will be used. The teeth will be divided into 3 experimental groups(10 in every group). Before cavity preparation, teeth will disinfected with 0.2% Chlorhexidine solution. After local anesthesia and rubber dam application, occlusal Class I cavities will prepare. Bleeding will be controlled with Saline irrigation, and a sterile cotton pellet is placed onto the pulp exposure sites. the teeth will be provisionally restored with Glass Inomer cement. Patients in all groups will return to the clinic for clinical examinations and extraction after 2 months. Inclusion criteria is age(18-32 years)؛ erupted third molar؛ closed apex؛ caries free؛ normal sign to vitality tests and exclusion criteria is external or internal resorptin؛ periapical lesion. Biodentin and Theracal are intervention groups and Pro root-MTA is control group.The main outcome measure is pulp health and dentin barrier formation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082420004N2**
Registration date: **2016-02-10, 1394/11/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-10, 1394/11/21

Registrant information

Name

Hengameh Bakhtiar

Name of organization / entity

Islamic Azad University of Tehran, faculty of dentistry

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2015-09-01, 1394/06/10

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical, radiological and histological evaluation of Pro root-MTA, Biodentine and Theracal in partial pulpotomy of human dental healthy pulp.

Public title

Evaluation of Pro root-MTA, Biodentine and Theracal in partial pulpotomy of human dental healthy pulp.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:age(18-32 years)؛ erupted third molar؛ closed apex؛ caries free؛ normal sign to vitality tests

Exclusion criteria: external or internal resorption, periapical lesion

Age

From **18 years** old to **32 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Moral Committee of Islamic Azad dental university of Tehran.

Street address

Azad dental school, #10 Neyestan, Pasdaran Ave, Tehran, Iran.

City

Tehran

Postal code

Approval date

2015-06-14, 1394/03/24

Ethics committee reference number

0821.P.166.5

Health conditions studied

1

Description of health condition studied

Vital pulp therapy.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pulp health(Post Operative sensitivity and pain).

Timepoint

After treatment, 1 weak later and before extraction.

Method of measurement

Vitality tests, cold test and EPT.

2

Description

Signs of periapical pathology.

Timepoint

Radiographs are taken before intervention and extraction.

Method of measurement

PA radiography.

Secondary outcomes

1

Description

Dentine barrier formation.

Timepoint

8 weeks after beginning treatment.

Method of measurement

Histologic examination after extraction.

Intervention groups

1

Description

In first group, Biodentin will be used for partial pulpotomy. Biodentin is new calcium silicate-based that is bioactive and non-toxic as demonstrated on human pulp cells. One single dose of liquid will be added to a capsule containing Biodentin and will be mixed for 30 seconds. Then a bulk of cement will be applied in the cavity and the setting time is 12 minutes.Then teeth will be filled with Glass Inomer.

Category

Treatment - Other

2

Description

In the second groupe, Theracal will be used for partial pulpotomy. Theracal is also a new light-cured resin-modified calcium silicate-filled base/liner material, which sets in 20 seconds. Theracal consists of a single paste that placing in 2mm layer. Then teeth will be filled with Glass Inomer.

Category

Treatment - Other

3

Description

Pro root-MTA will be used for partial pulpotomy in control group. it is a water based_material compound with bismuth oxide, tricalcium and dicalcium silicate and tricalcium aluminate. Open a pouch of 0.5 mg pro_root

MTA and dispense onto a mixing pad then pull of a Pro root_MTA liquid ampoule and gradually mix the liquid into the cement for about 1 minute till make them into a creamy consistency material. Then teeth will be filled with Glass Inomer.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad dental university of Tehran.

Full name of responsible person

Dr Hengameh Bakhtiar

Street address

Dental school, #10 Neyestan, Pasdaran ave, Tehran, Iran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Islamic Azad dental university of Tehran.

Full name of responsible person

Dr Hengameh Bakhtiar.

Street address

Dental school, #10 Neyestan, Pasdaran ave, Tehran, Iran.

City

Tehran

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, Islamic Azad dental university of Tehran.

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

Islamic Azad dental university of Tehran.

Full name of responsible person

Dr Hengameh Bakhtiar

Position

Endodontist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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