

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the effect of common direct pulp capping treatments and single-visit with MTA on human pupal response (invivo)

Protocol summary

Summary

The purpose of this clinical trial is to compare the effect of different direct pulp capping methods on human pulpal response in the terms of inflammation & dentinal bridge formation. Methods: Eight patients providing 32 sound first premolars are selected. As recommended by ISO / TC 7405 pulpal exposure will be performed through a class I cavity. Four groups of eight specimens each will be defined according to the pulp capping method. Group A, will receive chemical set calcium hydroxide (Dycal). Group B, will receive mineral Trioxide Aggregate (MTA) according to manufacturer's instruction. Group C, will receive MTA and after its primary setting, within 15 minutes, the cavity is restored in the same appointment. Group D, will receive Multical as a direct pulp capping agent. Specimens will be assessed in the terms of dentinal bridge formation, its resembles to natural dentin, its thickness and inflammatory pulpal response. The last item will be scored 0-3 in which 0 corresponds to none, 1 to minimal, 2 to moderate and 3 to severe inflammation. In case of an abscess or true tissue necrosis, a score of 4 will be given as recommended by ISO / TC 7405.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808132668N1**

Registration date: **2010-07-23, 1389/05/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-07-23, 1389/05/01

Registrant information

Name

Sepideh Banava

Name of organization / entity

Islamic Azad University, Dental Branch

Country

Iran (Islamic Republic of)

Phone

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Email address

dr.s.banava@dentaliau.ir

Recruitment status

Recruitment complete

Funding source

personal

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2010-09-21, 1389/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of common direct pulp capping treatments and single-visit with MTA on human pupal response (invivo)

Public title

Comparison of human pulpal response after pulpal exposure to common treatments and single-visit MTA

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Patients aging from 10 to 16; 2- Patients that need to extract 4 premolars for orthodontic purposes; 3-the teeth should be free of caries and clinical symptoms; 4-Through thermal tests and radiographic

examination absence of any pathology will be confirmed. Periapical radiographs demonstrating absence of any pathology, no sensitivity to percussion, palpation and biting, no sensitivity to cold after 5 seconds contact with Green Endo Ice refrigerant spray, heat sensitivity after applying tempered Gutta Percha for 10 seconds. Pulp vitality will be ascertained with a digital pulp tester; 5- Absence of any systemaic disorder; 6- No consumption of drugs of any kind; 6-All patients and their parents need to sign a fully informed consent. Exclusion Criteria: 1-If any of the teeth shows caries, restoration, crack or hypocalcification; 2-presence of aperiapical pathosis; 3- Teeth that seem sensitive to cold, hot, percussion or pressure; 4- any systemaic disorder 5- consumption of drugs of any kind.

Age

From **10 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

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

Islamic Azad University, Dental branch

Street address

No.4 , 10th Neyestan , Pasdaran St.

City

Tehran

Postal code

19585/175

Approval date

2010-10-02, 1389/07/10

Ethics committee reference number

پ/261/د

Health conditions studied

1

Description of health condition studied

Pulp Capping (Direct pulpal exposure)

ICD-10 code

Y56.7

ICD-10 code description

Dental drugs, topically applied

Primary outcomes

1

Description

histologic findings- dentinal bridge formation- dentinal bridge thickness

Timepoint

6weeks

Method of measurement

According to histological evaluation and ISO/DIS7405 we will give to non inflamed cases no points, mild cases 1 point, moderate cases 2 points, severe cases 3 points and necrosis 4 points. The specimens will be evaluated in the terms of dentinal bridge formation and its resemblance to natural dentin and also the thickness of the bridge.

Secondary outcomes

1

Description

clinical signs like sensitivity to cold , heat , percussion , palpation , etc

Timepoint

weekly

Method of measurement

physical exam

Intervention groups

1

Description

application of MTA in second group and 24 hour interval before restoration

Category

Other

2

Description

pulpal exposurein all groups

Category

Treatment - Surgery

3

Description

application of Dycal in first group

Category

Other

4

Description

application of MTA in third group and 15 minute interval before restoration

Category

Other

5

Description

application of Multical in forth group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental clinic of Islamic dental associatin of Iran

Full name of responsible person

Dr. S. Banava

Street address

No. 16 , Seventeenth street, Gandi street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

personal

Full name of responsible person

Dr Sepideh Banava

Street address

No 4 , 10th Neyestan st, Pasdaaran st

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

personal

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 University, Dental Branch

Full name of responsible person

Dr. Sepideh Banava

Position

Specialist in Restorative Dentistry, head of dental materials department, assitant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Dental school, Tehran Azad university

Full name of responsible person

Dr. Sepideh Banava

Position

assiatant professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Other areas of specialty/work

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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