Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 claas 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 resembeles 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

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Sepideh Banava
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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 orthidontic 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 systemayic 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 hypocalcifacation; 2-presence of aperiapical pathosis; 3- Teeth that seem sensitive to cold, hot, percussion or pressure; 4- any systemayic 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 thichness

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 resemblence 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
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Sponsors / Funding sources

1

Sponsor
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personal
Full name of responsible person
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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
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
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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