

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

comparing the effect of ProRoot MTA and MTA/Treated Dentin Matrix (TDM) on clinical and histologic manifestations of human healthy dental pulp

Protocol summary

Summary

The aim of this randomized clinical trial will comparing the effect of ProRoot MTA and MTA/Treated Dentin Matrix (TDM) on clinical and histologic manifestations of human healthy dental pulp. Healthy volunteers aged between 18 to 30, male or female with at least 3 intact third molars included in this study. Twenty human intact third molars will be randomly allocated into two experimental groups (n=10) either treated and capped with ProRoot MTA or MTA/Treated Dentin Matrix subsequent to partial pulpotomy treatment. Six weeks after treatment, clinical sign/symptoms and radiographic changes will be evaluated. The teeth will then be extracted and examined histologically for inflammatory status of the pulp and dentinal bridge formation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121415782N1**

Registration date: **2014-02-16, 1392/11/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-16, 1392/11/27

Registrant information

Name

Peyman Mehrvarzfar

Name of organization / entity

Tehran Medical Science Branch, Islamic Azad University

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University, Tehran Medical Science Branch

Expected recruitment start date

2014-01-20, 1392/10/30

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing the effect of ProRoot MTA and MTA/Treated Dentin Matrix (TDM) on clinical and histologic manifestations of human healthy dental pulp

Public title

comparing the effect of two different materials on human dental pulp

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patients between 18 to 30 years old; patients that have at least 3 mature and intact third molars to be extracted; healthy periodontal condition
exclusion criteria: systemic diseases; medication intake

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran Medical Science Branch,
Islamic Azad University

Street address

No.4, Neyestan1o Ave, Pasdaran street

City

Tehran

Postal code

19585/175

Approval date

2013-10-22, 1392/07/30

Ethics committee reference number

پ/214/د

Health conditions studied

1

Description of health condition studied

Human Pulp Regeneration

ICD-10 code

Y56.7

ICD-10 code description

Dental drugs, topically applied

Primary outcomes

1

Description

clinical signs and symptoms (sensitivity to cold test and percussion)

Timepoint

1,3,7,14,21,28,35 and42 days after partial pulpotomy

Method of measurement

pulp vitality tests including thermal tests,Electric pulp test,pain, percussion, palpation,radiography

2

Description

histologic pulp tissue evaluation including inflammation

Timepoint

day 42 after intervention

Method of measurement

light microscopic evaluation

3

Description

histologic pulp tissue evaluation including dentin bridge formation

Timepoint

day 42 after intervention

Method of measurement

light microscopic evaluation

Secondary outcomes

1

Description

histologic pulp tissue evaluation including pulp necrosis or abscess formation

Timepoint

after extraction(daye 42)

Method of measurement

light microscopic evaluation

Intervention groups

1

Description

intervention: ProRoot MTA/Treated Dentin Matrix in two separate layers of each 1mm thickness, pulpal layer includes TDM and then a layer of MTA covering it, for 6 weeks.

Category

Treatment - Drugs

2

Description

control: ProRoot MTA that covering the pulpal exposure in one layer of 2mm thickness

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Medical science Branch,Islamic Azad University

Full name of responsible person

Peyman Mehrvarzfar

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No.4, Neyestan10 Alley, Pasdaran Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

self-sponsored by researchers in study

Full name of responsible person

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Tehran Medical Science Branch, Islamic Azad University

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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

self-sponsored by researchers in study

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**

Tehran Medical science Branch, Islamic Azad University

Full name of responsible person

Sohrab Tour Savadkouhi

Position

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Web page address**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