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

Country

Iran (Islamic Republic of)

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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
د/214/پ

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 inflamation
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 abcess 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
Peyman Mehrvarzfar
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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
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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