

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Histologic response of human dental pulp to dexamethasone treatment following MTA-direct pulp capping and MTA-partial pulpotomy: A randomized clinical trial

#### Protocol summary

##### Summary

The aim of this randomized clinical trial was to histologically investigate the possible effects of dexamethasone application after MTA- DPC and PP in human premolar teeth. Methods and Materials: Forty intact premolar teeth will select from 10 healthy orthodontic patients that will candidates for extraction of four premolars; the teeth will randomize for DPC (n=20) or PP (n=20). After anesthesia and isolation, a class I cavity will prepare and buccal pulp horn will expose using a high speed ½ round high speed bur under copious water coolant. The buccal pulp horn exposure will pinpoint in size for DPC group, while whole head of the bur will enter into the pulpal horn in PP group. Subsequently, exposure site will seal using ProRoot MTA and cavities will restore with glass ionomer. After 60 days, the teeth will extract and 4 micron sections will prepare. Histologic evaluation will performe by an independent oral and maxillofacial pathologist. Kruskal-Wallis and Fisher exact tests will use for statistical analysis of the data (P=0.05).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014080618711N1**  
Registration date: **2014-08-22, 1393/05/31**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-08-22, 1393/05/31

##### Registrant information

Name

Seyed Amir Mousavi

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3673 6517

##### Email address

mousavi@dnt.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2014-08-20, 1393/05/29

##### Expected recruitment end date

2014-09-20, 1393/06/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Histologic response of human dental pulp to dexamethasone treatment following MTA-direct pulp capping and MTA-partial pulpotomy: A randomized clinical trial

##### Public title

effect of dexamethasone on dental pulp

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: The teeth must have no history of trauma; absence of caries; restorations; periodontal problems; Exclusion criteria: Patients with known allergy;

sensitivity; contraindications for use of dexamethasone

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 40

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mashhad University of Medical Sciences

##### Street address

Bolvar vakil abad

##### City

Mashhad

##### Postal code

#### Approval date

2012-10-27, 1391/08/06

#### Ethics committee reference number

910281

## Health conditions studied

### 1

#### Description of health condition studied

pulpitis

#### ICD-10 code

K04

#### ICD-10 code description

Diseases of pulp and periapical tissues

## Primary outcomes

### 1

#### Description

calcified bridge

## Timepoint

2 months

## Method of measurement

h and e staining

## Secondary outcomes

### 1

#### Description

tissue reaction

#### Timepoint

2 months

#### Method of measurement

microscope

## Intervention groups

### 1

#### Description

Forty intact premolar teeth will select from 10 healthy orthodontic patients that will candidates for extraction of four premolars; the teeth will randomiz for DPC (n=20) or PP (n=20). After anesthesia and isolation, a class I cavity was prepared and buccal pulp horn will expose using a high speed ½ round high speed bur under copious water coolant. The buccal pulp horn exposure will pinpoint in size for DPC group, while whole head of the bur will enter into the pulpal horn in PP group. The half of the DPC or PP groups, will receive dexamethasone in "solution" . Subsequently, exposure site was sealed using ProRoot MTA and cavities will restore with glass ionomer. After 60 days, the teeth were extracted and 4 micron sections prepared. Histologic evaluation will performe by an independent oral and maxillofacial pathologist.

#### Category

Treatment - Drugs

### 2

#### Description

for group 1: The buccal pulp horn exposure will pinpoint in size for DPC group

#### Category

Treatment - Drugs

### 3

#### Description

for group 2: whole head of the bur will enter into the pulpal horn in PP group

#### Category

Treatment - Drugs

### 4

#### Description

for goup 3:The half of the DPC group, will receive dexamethasone in "solution"

#### Category

Treatment - Drugs

## 5

### Description

for group 4:The half PP group , will receive dexamethasone in "solution"

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental Research Center of Mashhad University of Medical Sciences

##### Full name of responsible person

Seyed Amir Mousavi

##### Street address

Number 1 ; Koye Emamsadegh ; Isfahan ; Iran

##### City

isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Jamileh Ghodduzi

##### Street address

Iran , Mashhad , Vakilabad bolvar , Dental Reasearch Center

##### City

Mashhad

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad University of Medical Sciences

#### 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

Isfahan University of Medical Sciences

#### Full name of responsible person

Dr Seyed Amir Mousavi

#### Position

Assistant perofessor

#### Other areas of specialty/work

#### Street address

Number 1 , Koye emamsadegh , Isfahan , Iran

#### City

Isfahan

#### Postal code

8174663651

#### Phone

+98 31 3673 6517

#### Fax

#### Email

mousavi@dnt.mui.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Isfahan University of Medical Sciences

#### Full name of responsible person

Seyed Amir Mousavi

#### Position

Endodontist,assistant professor

#### Other areas of specialty/work

#### Street address

Number 1 , Koye emamsadegh , Isfahan , Iran

#### City

Isfahan

#### Postal code

8174663651

#### Phone

+98 31 3673 6517

#### Fax

#### Email

mousavi@dnt.mui.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Isfahan University of Medical Sciences

#### Full name of responsible person

Seyed Amir Mousavi

#### Position

Assistant professor

#### Other areas of specialty/work

#### Street address

Number 1 , Koye emamsadegh , Isfahan , Iran

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**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*