

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

**Histological study of Ca(OH)<sub>2</sub> effect and different concentrations of SIMVASTATIN on pulp-dentin complex response after Direct Pulp Capping . on primary molars of 7-9 years old children who had serial extraction treatment plan, hard tissue formation was evaluated.**

### Protocol summary

#### Summary

Aim: The aim of present study was to investigate pulp-dentin complex reactions following direct pulp capping (DPC) with calcium hydroxide [Ca(OH)<sub>2</sub>] and simvastatin as pulp-capping materials in the primary human molars. study procedure: Randomized, double blind, single study. 72 primary molar teeth which had to be extracted for orthodontic reasons were randomly allocated into four groups. Group I as a control, underwent DPC with calcium hydroxide. The dental pulp in group II, III and IV were directly capped with simvastatin-based materials at concentrations of 1, 5 and 10 µM/L, respectively. All of the teeth were restored with stainless steel crown. After a mean period of 7.41 months (6-9 months) teeth were extracted and processed for histological examination and categorized in terms of hard tissue formation and pulp inflammation.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2012071410276N1**

Registration date: **2012-09-16, 1391/06/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2012-09-16, 1391/06/26

#### Registrant information

##### Name

Ensiyeh Maljaei

##### Name of organization / entity

Dental Faculty of Tabriz Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 5965

##### Email address

joddd@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Dr. Mohammad reza Rashidi

##### Expected recruitment start date

2011-07-20, 1390/04/29

##### Expected recruitment end date

2011-10-29, 1390/08/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Histological study of Ca(OH)<sub>2</sub> effect and different concentrations of SIMVASTATIN on pulp-dentin complex response after Direct Pulp Capping . on primary molars of 7-9 years old children who had serial extraction treatment plan, hard tissue formation was evaluated.

##### Public title

Histological study of Ca(OH)<sub>2</sub> effect and different concentrations of SIMVASTATIN on pulp-dentin complex response after Direct Pulp Capping

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Cases were selected considering the following inclusion

criteria: 1.primary first and second molars. 2.deep caries but no indication for pulpotomy or pulp therapy. 3.teeth which had to be extracted to orthodontic treatment plan in close future but also had to be treated due to deep caries. 4.patient willingness. Exclusion criteria: 1. Teeth in which there is inflammation at the exposure site, or bleeding in an amount for a hyperemic or inflamed pulp 2. Necrotic or infectious pulps 3. Carious exposures.

#### Age

From **7 years** old to **9 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **72**

#### 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

Tabriz University of Medical Sciences Ethics Committee

##### Street address

Central building No.2- Tabriz University of Medical Sciences- University avenue

##### City

Tabriz

##### Postal code

5165665931

#### Approval date

2012-07-09, 1391/04/19

#### Ethics committee reference number

9162

## Health conditions studied

### 1

#### Description of health condition studied

Dental caries

#### ICD-10 code

K02

#### ICD-10 code description

Dental caries

## Primary outcomes

### 1

#### Description

Hard tissue formation

#### Timepoint

After 6-9 months as part of the orthodontic treatment

#### Method of measurement

Microscopic view

## Secondary outcomes

### 1

#### Description

Pulp inflammation

#### Timepoint

After 6-9 months as part of the orthodontic treatment

#### Method of measurement

Microscopic view

## Intervention groups

### 1

#### Description

Control group: Direct pulp capping by calcium hydroxide for 6-9 months. Direct pulp capping (DPC) involves the application of a medicament, dressing or dental material on the exposed pulp in an attempt to preserve its vitality

#### Category

Rehabilitation

### 2

#### Description

Intervention group (2): Direct pulp capping by 1 µM/L simvastatin for 6-9 months. Direct pulp capping (DPC) involves the application of a medicament, dressing or dental material on the exposed pulp in an

#### Category

Rehabilitation

### 3

#### Description

Intervention group (3): Direct pulp capping by 5 µM/L simvastatin for 6-9 months. Direct pulp capping (DPC) involves the application of a medicament, dressing or dental material on the exposed pulp in an

#### Category

Rehabilitation

### 4

#### Description

Intervention group (4): Direct pulp capping by 10 µM/L

simvastatin for 6-9 months. Direct pulp capping (DPC) involves the application of a medicament, dressing or dental material on the exposed pulp in an

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental faculty, Tabriz University of Medical Sciences

##### Full name of responsible person

Ensiyeh Maljaei

##### Street address

Department of pediatric dentistry- faculty of dentistry- Daneshgah Avenue

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. mohammadreza rashidi

##### Street address

Central building no 2 - Tabriz university - University avenue

##### City

Tabriz

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Naser Asl Aminabadi

##### Position

Pedodontist/professor

##### Other areas of specialty/work

##### Street address

Faculty of Dentistry- Daneshgah avenue

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##### Postal code

##### Phone

+98 41 1335 5965

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n-aminabadi@tbzmed.ac.ir

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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Post graduate student

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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*