Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 2026

Histological study of Ca(OH)2 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)2] 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

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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)2 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)2 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 tobe treated due to deep caries. 4.patient willfulness. 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 inflammaetion

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

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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