

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### Comparison of post-operative pain following pulpectomy of vital deciduous teeth in one or two sessions: a randomized clinical trial

#### Protocol summary

##### Summary

Objective: This clinical trial study to compare the pain is primary pulpectomies vital teeth in one session (pulpectomy and paste coated steel) and two sessions (treatment Endodontic treatment in a meeting and put the cover in the next session) is performed. Materials and Methods: In this study, 100 primary molars in children 12-6 years of age are enrolled. Each child with milk teeth need treatment pulpectomies in this study is vital. Treatment of a meeting like this; after caries removal and cavity preparation, root access with Barbad Broach out the pulp tissue, dental Canal after controlling bleeding dry channels, ZOE diluted mixture is then used to fill channels stainless steel is coated dental restoration. Two sessions of treatment consists of two stages in the first session and the second session of the pulp treatment is plated stainless steel.

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##### Recruitment status

**Recruitment complete**

##### Funding source

Kerman University of Medical Sciences

##### Expected recruitment start date

2016-12-10, 1395/09/20

##### Expected recruitment end date

2017-02-18, 1395/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016122231473N1**

Registration date: **2017-02-05, 1395/11/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-05, 1395/11/17

##### Registrant information

##### Name

Elham Farokhgisor

##### Name of organization / entity

Faculty of dentistry, Kerman

##### Country

Iran (Islamic Republic of)

##### Scientific title

Comparison of post-operative pain following pulpectomy of vital deciduous teeth in one or two sessions: a randomized clinical trial

##### Public title

Comparison of pain in root canal therapy of primary teeth in one or two visit

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: vital deciduous teeth with active bleeding during access cavity preparation, lack of clinical and radiographic evidence of pulpal necrosis, resorption of less than two third of the root length, restoration possible, cooperative child, at least one molar with evidence of irreversible pulpitis , e.g. sensitivity to cold or hot stimulus. Exclusion criteria: child with systemic diseases, follicular or dentigerous cyst below deciduous tooth, pathologic resorption of at least one third of root length with fistulous sinus tract, resorption of

more than two third of root length, isolation of tooth not possible, advanced internal resorption, periradicular lucency involving permanent tooth bud.

#### Age

From **6 years** old to **12 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research and Technology, Kerman University of Medical Sciences

##### Street address

Tahmasebabad Crossroads, Building Department, Research and Technology

##### City

Kerman

##### Postal code

#### Approval date

2016-05-09, 1395/02/20

#### Ethics committee reference number

IR.KMU.REC.1394.624

## Health conditions studied

### 1

#### Description of health condition studied

Pulp therapy in primary

#### ICD-10 code

K04.0

#### ICD-10 code description

Pulpitis

## Primary outcomes

### 1

#### Description

Pain relief after visit

#### Timepoint

one day-seven days

#### Method of measurement

VAS

## Secondary outcomes

### 1

#### Description

Pain relief

#### Timepoint

1-7 day

#### Method of measurement

VAS

## Intervention groups

### 1

#### Description

Control group:Pulpectomy treatment and insert the SSC in one visit

#### Category

Other

### 2

#### Description

Intervention group: Pulpectomy treatment in one session and the second session insert the SSC.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of dentistry, Kerman

##### Full name of responsible person

Dr Masoumeh Aminizadeh

##### Street address

Shafa Street, Faculty of dentistry

##### City

Kerman

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research and Technology Vice Chancellry, Kerman

University of Medical Sciences  
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 Dr Abbas Pardakhti  
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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**  
 Research and Technology Vice Chancellry, Kerman  
 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

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## Person responsible for scientific inquiries

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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*