

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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.

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

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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

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

Full name of responsible person

Dr Abbas Pardakhti

Street address

Tahmasebabad Crossroads, Building Department of Science and Technology of Kerman University of Medical Sciences

City

Kerman

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

Contact

Name of organization / entity

Kerman University of Medical Sciences -School of Dentistry

Full name of responsible person

Dr Masoumeh Aminizadeh

Position

resident of pediatric dentistry

Other areas of specialty/work

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Contact

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Position

Full Professor Endodontist

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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