

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Radiographic Evaluation Of Pulpectomies In Primary Molars Using Five Filling Systems: An in-vivo study

Protocol summary

Summary

The purpose of this in-vivo study is comparison of different methods of root canal obturation in primary molars with digital radiography. This study is randomized and single blind. 60 primary mandibular molars from healthy cooperating children (4-7 years) who have first or second molars indicated for pulpectomy will be selected. In each tooth 2 canals will be assessed. After obtaining consent from their parents or guardians, the teeth will be treated under local anesthesia and randomly divided into 5 groups. The root canals in each group will be filled with Zinc oxide-eugenol paste. The paste will be transported into the canals using one of the randomly assigned methods: 1-local anesthetic syringe 2-Insulin syringe 3-NaviTip system 4-Condensing with plugger 5-lentulo spiral. The access cavity will be filled with IRM and the crown will be restored with S.S.C. Post-operative digital radiographs will be taken. All assessments will be performed by two operators who are blind to the treatment groups. The radiographs will be analyzed to assess presence of voids, number and size of voids, and canal obturation quality. The quality of canal obturation is based on the amount of paste in the canal. If less than one-half of the canal filled, the score is 1. If greater than one-half but less than two-thirds filled, the score is 2. Optimal filling (0-1.5 mm shorter than the apex) is score 3. Over filling belongs to score 4.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031012773N1**

Registration date: **2013-04-29, 1392/02/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-04-29, 1392/02/09

Registrant information

Name

Zeinab Bouzarjomehri

Name of organization / entity

Dental college of Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of dental college of Isfahan University of Medical Sciences

Expected recruitment start date

2013-05-05, 1392/02/15

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Radiographic Evaluation Of Pulpectomies In Primary Molars Using Five Filling Systems: An in-vivo study

Public title

Evaluation of different methods of root canal treatment in primary dentition

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: healthy children who have first or second molars indicated for pulpectomy according to the following 1- spontaneous pain 2-continuous bleeding after amputation of coronal pulp or pus discharge from the canal 4- tenderness to percussion or palpation 5- redness and swelling of the vestibule. Exclusion criteria :systemic disease- uncooperative child- unrestorable tooth-chronic abscess- internal,external and physiologic root resorption

Age

From **4 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Vice chancellor for research of Dental College of Isfahan university of Medical Sciences

Street address

Dental College, Isfahan University of Medical Sciences, Azadi square(Darvazeh Shiraz), Isfahan

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Postal code

8174673461

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

391274

Health conditions studied

1

Description of health condition studied

Disease of pulp and periapical tissue

ICD-10 code

k04.0

ICD-10 code description

pulpitis

Primary outcomes

1

Description

level of canal obturation

Timepoint

after intervention and taking radiograph

Method of measurement

from radiograph in term of grade(1 to 4)

Secondary outcomes

1

Description

number and size of voids

Timepoint

after intervention and taking radiograph

Method of measurement

number in term of numeral_size in term of square millimeter

Intervention groups

1

Description

Endodontic treatment in order to Remove the infection from the root canal in all experimental groups

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental College of Isfahan University of Medical Sciences

Full name of responsible person

Doctor Nosrat Nourbakhsh-Pediatric Dentist-Assistant professor

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Isfahan university, Azadi square(Darvazeh Shiraz), Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Dental College, Isfahan University, Azadi square, Isfahan

Full name of responsible person

Doctor Omid Savabi-Vice chancellor for research chief of Dental College of Isfahan University of Med

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Grant name**Grant code / Reference number**

391274

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

Yes

Title of funding source

Vice chancellor for research, Dental College, Isfahan University, Azadi square, Isfahan

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**

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Full name of responsible person

Doctor Nosrat Nourbakhsh

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Pediatric Dentist, Assistant Professor

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Web page address**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

