

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

comparison of outcome of apexogenesis treatment with mineral trioxide aggregate and new endodontic cement (in-vivo study)

Protocol summary

Summary

In this study, we are going to compare the clinical and radiographic outcomes of apexogenesis treatment with MTA and NEC. 40 young patients with deep caries or traumatic exposure on immature permanent teeth will be entered the study. These teeth must have vital pulps with no clinical or radiographic signs of necrosis or infection. Subjects will be randomly divided to MTA and NEC groups. Clinical and radiographic follow ups will be done at 3, 6 and 12 months in order to evaluate the clinical outcomes of treatment and the quality of root development.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805242345N1**
Registration date: **2009-10-12, 1388/07/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-10-12, 1388/07/20

Registrant information

Name

Ali Nosrat

Name of organization / entity

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Rafsanjan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences, Endodontic
Research Centre, Shahid Beheshti University of Medical
Sciences

Expected recruitment start date

2009-08-01, 1388/05/10

Expected recruitment end date

2009-10-01, 1388/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of outcome of apexogenesis treatment with
mineral trioxide aggregate and new endodontic cement (
in-vivo study)

Public title

Apexogenesis with mineral trioxide aggregate or new
endodontic cement.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: open apex teeth with caries exposure
or traumatic exposure of the pulp Exclusion criteria:
teeth with sign and symptoms of infection, periapical
radiolucency, or sinus tract

Age

From **6 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rafsanjan University of Medical Sciences

Street address

Rafsanjan

City

Rafsanjan

Postal code

Approval date

2009-05-18, 1388/02/28

Ethics committee reference number

345

Health conditions studied

1

Description of health condition studied

Pulpitis in open apex tooth

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Radiographic success of apexogenesis treatment

Timepoint

3, 6, 12 months after intervention

Method of measurement

Expert opinion

Secondary outcomes

1

Description

Clinical success

Timepoint

1 day, 3, 6 and 12 months after intervention

Method of measurement

clinical examination

Intervention groups

1

Description

Apexogenesis with NEC

Category

Treatment - Other

2

Description

Apexogenesis with MTA

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rafsanjan University of Medical Sciences, Endodontic Research Centre, Shahid Beheshti University of

Full name of responsible person

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences, Iranian Center for Endodontic Research (Shahid Beheshti Un

Full name of responsible person

Ali Nosrat

Street address

Rafsanjan University of Medical Sciences, Dental School

City

Rafsanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan University of Medical Sciences, Iranian Center for Endodontic Research (Shahid Beheshti Un

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**

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Nosrat

Position

Assistant prof./DDS,MS.

Other areas of specialty/work**Street address**

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Iranian Center for endodontic Research

Full name of responsible person

Saeed Asgary

Position

Prof. of Endodontics/ DDS, MS

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Web page address**Person responsible for updating data****Contact****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