Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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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Iran (Islamic Republic of)

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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
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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