Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the Effect of Calcium Hydroxide and Nano Calcium Hydroxide on Regeneration of Immature Permanent Teeth : A Clinical Pilot Study

Protocol summary

Study aim

The object of this study is to compare the effect of calcium hydroxide and nano calcium hydroxide on the regeneration of nonvital immature teeth.

Design

A randomized clinical trial will be performed on 24 patients that were randomly divided as a control and a parallel experimental group, triple blinded that were randomized by random.org software

Settings and conduct

In this study that will perform in shiraz dental school, 24 patients would be selected to be treated with two different medicine for regeneration of necrotic pulp in the way that patients, practitioners, and evaluators are blind

Participants/Inclusion and exclusion criteria

Patients with a restorable tooth with necrotic pulp and open apices, with or without radiographic evidence of periapical lesion, and a negative response to vitality tests without any medical history of systemic conditions will be included in the study. Teeth having periodontal disease, internal o external resorption, and fracture in the root will exclude from the study

Intervention groups

Intervention group: Nano calcium hydroxide paste with a creamy consistency will use for disinfection of root canal in the regeneration of a tooth with necrotic pulp. Control group: Calcium hydroxide paste with a creamy consistency will use for disinfection of root canal in the regeneration of a tooth with necrotic pulp. Medicaments of both groups will deliver into the root canal at the first appointment and will irrigate from the root canal after three weeks. the cervical portion of the root will restore with MTA as a sealing material

Main outcome variables

Pulp revitalization Root dentin diameter chage Root length change

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210227050512N1**
Registration date: **2021-08-08, 1400/05/17**
Registration timing: **prospective**

Last update: **2021-08-08, 1400/05/17**
Update count: **0**

Registration date

2021-08-08, 1400/05/17

Registrant information

Name

Safoora Sahebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3626 3193

Email address

sahebisafoora@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-14, 1400/06/23

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effect of Calcium Hydroxide and Nano Calcium Hydroxide on Regeneration of Immature Permanent Teeth : A Clinical Pilot Study

Public title
Effect of Nano Calcium Hydroxide in tooth pulp Regeneration

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Non-Vital Permanent teeth with Open Apex (file size number equal or more than 60) With or Without Radiographic Radiolucency Negative Response to Pulp Vitality Test Restorable Tooth No Systemic Conditions Patients' age between 6-16 years old

Exclusion criteria:
With Radiographic Evidence of Internal or External Resorption With Root Fractures With Periodontal Involvement Those Who Do Not Cooperate

Age
From **6 years** old to **16 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual Block randomization method was used for the Patient's Allocation into two groups with a 1:1 Ratio by RANDOM.ORG Software. Participants were divided into two Groups of Pulp revitalization with calcium hydroxide and nano calcium hydroxide paste.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Calcium hydroxide and nano calcium hydroxide pastes will give to the practitioner in a similar volume, consistency, and color, as well as a similar container. Participants (patients) will not be aware of the type of material used in the therapy as same as the evaluators of the treatment results. The researcher is the only one who knows which medicament has been used for each patient and leads the research.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of shiraz university of medical science

Street address
Shiraz Dental School, Ghasrodasht Street, Shiraz

City
Shiraz

Province
Fars

Postal code
7195615878

Approval date
2021-05-26, 1400/03/05

Ethics committee reference number
IR.SUMS.DENTAL.REC.1400.029

Health conditions studied

1

Description of health condition studied
Immature tooth pulp necrosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pulp revitalization

Timepoint
Evaluation of pulp revitalization would perform in 3, 6, and 9 month after treatment.

Method of measurement
Cold test and electrical pulp test for evaluating pulp revitalization

2

Description
Root dentin diameter change

Timepoint
Evaluation of changes in root dentin diameter would perform in 3, 6, and 9 month after treatment.

Method of measurement
The difference between the external root thickness and the width of the pulpal area of the canal will evaluate radiographically.

3

Description

Root length chages

Timepoint

Evaluation of changes in root length would perform in 3, 6, and 9 month after treatment.

Method of measurement

Distance between Cemento-Enamel-Junction on the mesial portion and the mesial and distal point at the end of the apex will evaluate radiographically.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Regeneration treatment of dental pulp would perform using nano-calcium hydroxide paste (Polymer and Petrochemical Institute, Tehran, Iran) with a creamy consistency obtained by a combination of nano-calcium hydroxide powder and 0.9% saline in three to one ratio, According to the American Association of Endodontics protocol.

Category

Treatment - Drugs

2

Description

Control group: Regeneration treatment of dental pulp would perform using calcium hydroxide paste (Merck, Darmstadt, Germany) with a creamy consistency obtained by a combination of calcium hydroxide powder and 0.9% saline in three to one ratio, According to the American Association of Endodontics protocol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Dental School

Full name of responsible person

Dr Safoora Sahebi

Street address

Shiraz Dental School, Ghasrodasht Street, Shiraz

City

Shiraz

Province

Fars

Postal code

7196515878

Phone

+98 71 3193 3626

Email

sahebisafoora@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Abbas Rezaianzade

Street address

Shiraz medical School, Zand Street

City

Shiraz

Province

Fars

Postal code

7195615878

Phone

+98 71 7282 3235

Email

rezaiana@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Safoora Sahebi

Position

Associated Professor of Endodontics, Shiraz University of Medical Science

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Shiraz Dental School, Ghasrodasht Street, Shiraz

City

Shiraz

Province

Fars

Postal code

7195615878

Phone
+98 71 3194 3626
Email
sahebisafoora@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Safoora Sahebi
Position
Associated Professor of Endodontics, Shiraz University of Medical Science
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shiraz Dental School, Ghasrodasht Street, Shiraz
City
Shiraz
Province
Fars
Postal code
7195615878
Phone
+98 71 3194 3626
Email
sahebisafoora@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Safoora Sahebi
Position
Associated Professor of Endodontics, Shiraz University of Medical Science
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shiraz Dental School, Ghasrodasht Street, Shiraz
City
Shiraz
Province
Fars
Postal code
7195615878
Phone
+98 71 3194 3626
Email
sahebisafoora@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The results of the study consist of clinical and radiographic findings of participants due to the kind of materials which were used.
When the data will become available and for how long
6 months after publication
To whom data/document is available
there is no limit.
Under which criteria data/document could be used
with referencing of the article
From where data/document is obtainable
the corresponding author
What processes are involved for a request to access data/document
the written request should be sent through an email to the corresponding author - data will give in one month after the permission of all authors
Comments