Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effect of Double Antibiotic Paste Alone or in Combination with Metformin on Regeneration of Non-Vital Immature Teeth: A Pilot Clinical Study

Protocol summary

Study aim

the objective of this study is to compare the effect of Double Antibiotic Paste alone or in combination with Metformin 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, in Shiraz Dental School, 24 patients would be selected in order to be treated with two different regeneration medicine in the way that patients, the practitioner, and observers are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Nonvital permanent restorable teeth with open apices with or without radiographic evidence of periapical lesions, negative response to vitality tests, and the participant gave no contributory systemic medical history. Exclusion criteria: Severe Periodontal Disease, Internal or External Root Resorption

Intervention groups

Intervention Group: Using the combination of Metformin 500 mg (Abidi co.) and Double Antibiotic Paste (DAP) as a disinfectant in the Regeneration of Nonvital Pulp; Control group: use of the DAP alone as a disinfectant in the Regeneration of Necrotic Pulp as a suggested protocol. DAP is a combination of 250 mg Metronidazole(Kosar co.) and 500 mg Ciprofloxacin(Tolidaru co.) and has been proved to have an antibacterial effect and is used in the first session of Regeneration protocol and washed out three weeks later, the cervical segment of root canal system would be sealed with MTA (Angelus, Londrina, PR, Brazil).

Main outcome variables

Pulp Revitalization, Dentin Diameter Change, Root Length Change

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200120046197N1**
Registration date: **2021-02-26, 1399/12/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-26, 1399/12/08**
Update count: **0**

Registration date

2021-02-26, 1399/12/08

Registrant information

Name

Safoora Sahebi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the Effect of Double Antibiotic Paste Alone or in Combination with Metformin on Regeneration of Non-Vital Immature Teeth: A Pilot Clinical Study

Public title
Effect of Metformin Combination with Double Antibiotic Paste (DAP) in Tooth Pulp Regeneration

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Non- Vital Permanent Teeth with Open Apex(File size equal or more than 60) With or without Radiographic Radiolucency Negative Response to Pulp Vitality Test Restorable Tooth No Systemic Conditions

Exclusion criteria:
Severe periodontal disease, Internal and external root resorption

Age
From **7 years** old to **11 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
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 Double Antibiotic Paste Revascularization techniques with and without Metformin.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The Double Antibiotic pastes with the same Color, Consistency, and Volume are delivered in the same Container to the Practitioner. Participants (patients) have no idea about the materials that were used for them. Observers have no Idea about the materials which are used for the Patients. The Researcher is the only one who knows about suggested Materials which is 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 Sciences

Street address
Shiraz Dental School , GHasrdasht St..reet

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Province
Fars

Postal code
71956-15878

Approval date
2020-01-05, 1398/10/15

Ethics committee reference number
IR.SUMS.DENTAL.REC.1398.139

Health conditions studied

1

Description of health condition studied
Tooth Pulp Necrosis

ICD-10 code
-

ICD-10 code description
-

Primary outcomes

1

Description
pulp revitalization

Timepoint
Before intervention and patient follow up for 3 and 12 months after intervention

Method of measurement
Clinical And Radiographic Assessment

2

Description
Changes in diameter of root dentin with the regenerated tissues

Timepoint
Before intervention and patient follow up for 3 and 12 months after intervention

Method of measurement
Clinical And Radiographic Assessment

3

Description

Changes the length of root with the regenerated tissues

Timepoint

Before intervention and patient follow up for 3 and 12 months after intervention

Method of measurement

Clinical And Radiographic Assessment

Secondary outcomes

empty

Intervention groups

1

Description

Control group: the tooth is anesthetized, isolated, and accessed. After determining the working length, the canals should be copiously irrigated with NAOCL 1.5%followed by 17% EDTA. Canals were dried with sterile paper points and double antibiotic paste (DAP) as a mixture of Ciprofloxacin 500 mg (Tolidaru Co.) and Metronidazole 250mg (Kosar Co.) at the concentration of 1mg/ml is placed into the canals for 3-4weeks. In the second appointment, canals should be irrigated with 17%EDTA, and after the creation of bleeding with a No.25 file, on top of the coagulum, about 3 mm of MTA is then placed.

Category

Treatment - Drugs

2

Description

Intervention group: the tooth is anesthetized, isolated, and accessed. After determining the working length, the canals should be copiously irrigated with NAOCL 1.5%followed by 17% EDTA. Canals were dried with sterile paper points and double antibiotic paste (DAP) as a mixture of Ciprofloxacin 500 mg (Tolidaru Co.) and Metronidazole 250mg (Kosar Co.) Adding Metformin 500mg (Abidi Co.) with the same volume of antibiotics at the concentration of 1mg/ml is placed into the canals for 3-4weeks. In the second appointment, canals should be irrigated with 17%EDTA, and after the creation of bleeding with No.25 file, on top of the coagulum, about 3 mm of MTA is then placed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Dental School

Full name of responsible person

Dr. Fariborz Moazami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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. Fariborz Moazami

Position

Full Professor of Endodontics , Shiraz University of Medical Sciences

Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

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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 result of study consist of clinical and radiographic findings of participants due to the kind of materials which was used
When the data will become available and for how long
6 months after publishing
To whom data/document is available
No limit
Under which criteria data/document could be used
With referencing of the article
From where data/document is obtainable
Corresponding author
What processes are involved for a request to access data/document
Written request by email for corresponding author. One month after the permission of all authors
Comments