

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Regeneration of dental pulp complex in closed apex necrotic teeth using fibrin hydrogel.

Protocol summary

Study aim

The use of dental pulp complex in closed apex necrotic teeth with using fibrin hydrogel for regeneration of dental pulp.

Design

The participants who meet inclusion criteria will be randomized in two groups, the experimental group and the control group. The outcome will be assessed during recall examinations and after extraction, included clinical examinations, taking dental x-ray and histological tests. Selection and exclusion of subjects (experimental n:Δ, control n:Δ). If the root canal treatment with stem cells is successful, the teeth will be healthy like other teeth, and if the root canal treatment is not successful, the standard root canal treatment will be done free of charge.

Settings and conduct

Tehran University of Medical Sciences- Regenerative Medicine and stem cell Research Center The study is designed as a Clinical trial study. The participants who meet inclusion criteria will be randomized in two groups.

Participants/Inclusion and exclusion criteria

The main inclusion criteria of the study before randomization: Patients with single-rooted teeth number 1, 2 and 3 with irreversible pulpitis (need for root canal treatment) The main exclusion criteria of the study before randomization: Patients with perforation of the tooth from the pulp cavity through the tip of the root, which exposes the tissue to the material in the oral cavity.

Intervention groups

The experimental group received the proposed intervention (root restoration method using fibrin hydrogel) and the control group received the standard root restoration treatment.

Main outcome variables

Pulp evaluation will done by radiographic and clinical examination. Signs, symptoms, apical healing, and vitality will be compared with preoperative examinations. To evaluate odontoblasts and fibroblasts, extracted teeth

will be used in-vitro, and the expression of genes will be evaluated in a3D environment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230513058168N1**

Registration date: **2023-06-11, 1402/03/21**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-11, 1402/03/21**

Update count: **0**

Registration date

2023-06-11, 1402/03/21

Registrant information

Name

Jafar Ai

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

jafar_ay2000@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-14, 1402/02/24

Expected recruitment end date

2023-10-14, 1402/07/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Regeneration of dental pulp complex in closed apex necrotic teeth using fibrin hydrogel.

Public title

Restoration of dental pulp using hydrogel

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients must be systemically healthy, Class I dental category Involved teeth must have no periodontal disease detectable by periodontal examination. Patients must present with radiographic signs of endodontic disease (i.e., necrotic pulp with periapical radiolucency) One-rooted teeth number ١, ٢ and ٣ with irreversible pulpitis (need root canal treatment)".

Exclusion criteria:

Presence of any disease or medication that alters the immune system or interferes with healing ability
Smokers (more than ١٠ cigarettes per day) External or internal tooth resorption Tooth perforation from the pulp cavity through the tip of the root exposing the tissue to material in the oral cavity. Pregnant or nursing mothers because hormonal factors may influence the condition. Allergies or adverse reactions to local anesthetic medications Patients under the age of ١٨ Patients with an ASA Classification II or higher I. Cardiovascular Disease Disable or mental illness Osteoporosis

Age

From **18 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

The study is designed as a Clinical trial study. The participants who meet inclusion criteria will be randomized in two groups, the experimental group receives the proposed intervention a (regenerative endodontic procedure using Fibrin hydrogel), and the control group receives conventional regeneration therapy (blood clot). The outcome will be assessed during recall examinations and after extraction, included clinical examinations, taking dental x-ray and histological tests. Selection and exclusion of subjects (experimental n:٥, control n:٥). If the root canal treatment with stem cells is successful, the teeth will be healthy like other teeth, and if the root canal treatment is not successful, the standard root canal treatment will be done free of charge.

Blinding (investigator's opinion)

Double blinded

Blinding description

10 patients are placed in two groups of 5 for study. The studied groups will include 5 people receiving the root restoration method using fibrin hydrogel, 5 people receiving standard root canal treatment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran National committee for Ethics in Biomedical research

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2023-05-13, 1402/02/23

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.026

Health conditions studied**1****Description of health condition studied**

teeth with with irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes**1****Description**

Radiographic observations

Timepoint

Before the intervention and 1 week, 3 months and 6 months after the intervention

Method of measurement

Radiographic observations

2

Description

Examination of signs of apical healing and dental vital signs

Timepoint

Before the intervention and 1 week, 3 months and 6 months after the intervention

Method of measurement

Routine dental vital test methods.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Suggested root canal treatment intervention using 1 million cord stem cells in 300 microliters of fibrin hydrogel containing 300 micrograms of exosome and growth factor (NGF - VEGF) per dental canal.

Category

Treatment - Other

2

Description

Control group: Standard root canal treatment

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences

Full name of responsible person

Neda Bayat

Street address

No.88, Italya St., Ghods St., Keshavarz Blvd., Tehran, school of advanced technologies in medicine Tehran University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of San Francisco

Full name of responsible person

MiKe Sabeti

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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

University of San Francisco

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Foreign

Category of foreign source of funding

UN agencies and international organizations

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Neda Bayat

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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