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:۵, control n:۵). 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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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 ۱, ۲ and ۳ 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 ۱۰ 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 ۱۸ Patients with an ASA Classification II or higherI. 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:۵, control n:۵). 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
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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
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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

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Professor

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Dentistry

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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