

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Clinical Trial evaluation of alveolar bone repair using self-assembling peptide nanofiber

Protocol summary

Study aim

Investigating the effect of self-assembling peptide nanofiber on the repair of the jaw bone

Design

This study will be performed in a phase 2 clinical trial and double-blind. The doctor and statistical specialist will not be aware of the materials and groups. The sample size will be 12 people. According to calculations at Sealedenvelop.com, the selected rendering will be done in 6 groups of 2. Parallel groups include 1- Self-assembled nanofiber peptide group 2- PBS

Settings and conduct

Sampling and surgeries will be performed at the Tehran University of Medical Sciences. After tooth extraction and implantation of biomaterials, on the first day, 7 and 14 using the oral scanner in terms of : 1. infection 2. The amount of soft tissue formation They will be studied in comparison with the control group. Then, after 8 weeks, the amount of bone regeneration in the area will be evaluated using CBCT. Physicians and statisticians will not be aware of the materials and groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria 1. Age 18 to 70 years 2. Gender: male and female 3. They need tooth extraction 4. The patient has oral and dental hygiene Exclusion Criteria 1. Alcohol consumption 2. Pregnancy and breastfeeding 3. Uncontrolled diabetes 4. Autoimmune diseases 5. Cancer and undergoing chemotherapy

Intervention groups

1. An osteogenic cocktail of self-assembling peptide nanofiber (the company-made) 2. PBS is placed in a single dose (0.5 cc) to repair the tooth-extracted cavity and is investigated for 2 months.

Main outcome variables

1. Infection 2. The amount of soft tissue formation 3. Bone regeneration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210526051407N2**

Registration date: **2022-07-28, 1401/05/06**

Registration timing: **prospective**

Last update: **2022-12-09, 1401/09/18**

Update count: **1**

Registration date

2022-07-28, 1401/05/06

Registrant information

Name

Shima Tavakol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

tavakol.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-01, 1401/05/10

Expected recruitment end date

2023-08-01, 1402/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial evaluation of alveolar bone repair using self-assembling peptide nanofiber

Public title

Bone regeneration using self-assembling peptide nanofiber

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient has good oral and dental hygiene Patient will require tooth extraction

Exclusion criteria:

Alcohol consumption Pregnancy and lactation Uncontrolled diabetes Autoimmune diseases Cancer and undergoing chemotherapy

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

Selective randomization will be performed based on calculations at Sealedenvelop.com. Randomization will be done in 6 groups of 2 blocks in the form of A and B according to which patients will receive medication interventions.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding is two-way. 1- The doctor who places the material in the tooth cavity does not know the type of implanted material as a clinical caregiver. 2- The statistical expert who analyzes the results does not know about the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Iran University of Medical

Sciences

Street address

Iran University of Medical Sciences Shahid Hemmat Highway Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2022-07-26, 1401/05/04

Ethics committee reference number

IR.IUMS.REC.1401.355

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

Bone resorption in the jaw

ICD-10 code

M96.6

ICD-10 code description

Fracture of bone following insertion of orthopedic implant, joint prosthesis, or bone plate

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

Infection

Timepoint

The Zero, 7th and 14th days

Method of measurement

Oral Scanner

2**Description**

Repair of soft tissue

Timepoint

The Zero, 7th and 14th days

Method of measurement

Oral Scanner

Secondary outcomes**1****Description**

Bone Regeneration

Timepoint

After 2 months

Method of measurement

Cone-beam computed tomography (CBCT)

Intervention groups

1

Description

Intervention group: Osteogenic cocktail of self-assembling peptide nanofiber (the company-made) is placed in a single dose (0.25 cc) to repair the extracted tooth cavity and is evaluated for 2 months.

Category

Treatment - Drugs

2

Description

Control group: PBS is placed in a single dose (0.25 cc) to repair the extracted tooth cavity and is evaluated for 2 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences- Dental Research Institute

Full name of responsible person

Shima Tavakol

Street address

Dental Implant Institute, Dentistry School, Qods st, Enghelab st, Tehran

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2

Recruitment center

Name of recruitment center

Clinic of Dr. Hamidreza Barikani

Full name of responsible person

Dr. Hamidreza Barikani

Street address

Floor 1, No 4, Sattari BLVD, Jordan St, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Keyvani

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Keyvanlab@yahoo.com

Web page address

Grant name

Grant code / Reference number

1400-3-99-22545

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Knowledge enterprise company "Tavakol Pars Biomimetic Technologies Company

Full name of responsible person

Shima Tavakol

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No 5, Amirkabir st, Kashan, Isfahan, Iran

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Kashan

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shima.tavakol@yahoo.com

Web page address

<http://nanomimetic.com>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Knowledge enterprise company "Tavakol Pars
Biomimetic Technologies Company

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shima Tavakol

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Nanotechnology

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Associate Professor

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available