Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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 uing 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
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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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Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
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Fax
+98 21 8862 2703
Email
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
Street address
No 5, Amirkabir st, Kashan, Isfahan, Iran
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Kashan
Province
Isfehan
Postal code
8718693111
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Email

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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Full name of responsible person

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Position

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Latest degree

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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

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