

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Evaluation of clinical trial of self-assembling peptide nanofiber in sinus cavity repair

Protocol summary

Study aim

Evaluation of the effect of self-assembling peptide nanofibers in sinus cavity repair

Design

This study will be performed in phase 1-2 clinical trial and double-blind. The doctor and statistical specialist will not be aware of the materials and groups. The sample size will be 18 people. According to calculations at Sealedenvelop.com, the selected rendering will be done in 6 groups of 3. Parallel in groups include: 1- Bone powder 2- Self-assembled nanofiber peptide group 3- Combined group of bone powder and nanofiber peptide in proportion to ½

Settings and conduct

Sampling and surgeries will be performed at Tehran University of Medical Sciences. After surgery and implantation of biomaterials, after 2 weeks and 6 months, the following examinations will be performed: 1- Evaluation of pain and wound healing after 2 weeks 2- Evaluation of changes in vertical bone height, implant stability and monitoring of osteointegration after 6 months 3- Qualitative histomorphometric analysis after implantation Physicians and statisticians will not be aware of the materials and groups.

Participants/Inclusion and exclusion criteria

Inclusion factors: 1. Age 18 years to 70 years 2. Gender: male and female 3. Need sinus augmentation 4. The height between the maxillary sinus and the alveolar crown should be less than 8 mm 5. The patient has oral health 6. Do not have maxillary sinus diseases Exclusion factors 1. Smoking and tobacco 2. Pregnancy and lactation 3. Uncontrolled diabetes 4. Immune diseases 5. Cancer and undergoing chemotherapy

Intervention groups

1- Bone powder 2- Self- assembling peptide nanofiber 3- combination of bone powder and self- assembling peptide nanofiber

Main outcome variables

1- Pain 2- Wound healing 3- Stability of the implant 4-

Quality of bone tissue 5- Amount of vertical height

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210526051407N1**

Registration date: **2021-06-27, 1400/04/06**

Registration timing: **prospective**

Last update: **2022-12-01, 1401/09/10**

Update count: **1**

Registration date

2021-06-27, 1400/04/06

Registrant information

Name

Shima Tavakol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-06, 1400/04/15

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clinical trial of self-assembling peptide nanofiber in sinus cavity repair

Public title

Evaluation of clinical trial of self-assembling peptide nanofiber in sinus cavity repair

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient will require sinus augmentation bone height between alveolar crest and maxillary sinus less than 8 millimetres. Patient has good oral and dental hygiene Do not have maxillary sinus diseases

Exclusion criteria:

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

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **18**

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 3 blocks in the form of A, B and C, 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 sinus 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

۱۴۳۹۶۱۴۵۳۵

Approval date

2021-06-07, 1400/03/17

Ethics committee reference number

IR.IUMS.REC.1400.218

Health conditions studied

1

Description of health condition studied

Bone resorption in the maxilla

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

The fourteenth day

Method of measurement

McGill Pain Questionnaire (MPQ)

2

Description

Wound healing

Timepoint

The fourteenth day

Method of measurement

Using dental tweezers by examining alveolar osteitis based on BLUM'S criteria

3

Description

The amount of vertical height

Timepoint

Baseline and after 6 months

Method of measurement

CBCT

4

Description

Implant stability

Timepoint

After 6 months

Method of measurement

OSTELL

5**Description**

Bone tissue quality

Timepoint

Post-implantation

Method of measurement

Tissue staining

Secondary outcomes

empty

Intervention groups**1****Description**

Second Intervention group: Self-assembling peptide nanofiber (the company-made) is placed in a single dose (1 ml) to repair the sinus cavity and is tested for 6 months.

Category

Treatment - Drugs

2**Description**

Third Intervention group: The combined group of bone powder (0.5 gr) and Self-assembling peptide nanofiber (0.5 ml) in a single dose is placed to repair the sinus cavity and is examined for 6 months.

Category

Treatment - Drugs

3**Description**

Control group: Bone powder of Iranian Tissue Product Company is placed in a single dose (one gram) to repair the sinus cavity and is examined for 6 months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Iran University of Medical Sciences

Full name of responsible person

Shima Tavakol

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Web page address**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**

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Full name of responsible person

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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

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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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

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Nanotechnology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available