# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**

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Iran (Islamic Republic of)

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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 Sceinces

**Street address**
Iran University of Medical Sciences Shahid Hemmat Highway Tehran

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Tehran

**Province**
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**Postal code**
۱۴۴۹۶۱۴۵۳۵

**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**
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**2**

**Recruitment center**
**Name of recruitment center**
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## Sponsors / Funding sources

**1**

**Sponsor**
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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**
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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**
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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