Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial study of bone repair product NMImETIC Peptide Nanofibers in Patients with Leg Length Discrepancy

Protocol summary

Study aim
To investigate the bone regeneration efficacy of NMImETIC peptide nanofibers To assess callus formation before and after the application of NMImETIC peptide nanofibers

Design
This study is a prospective Phase 1 clinical trial. The study population will include patients presenting with impaired bone healing at the fracture site. Based on the study conducted at the Royan Institute (NCT Identifier: NCT01210950), a sample size of 6 patients was determined, with outcomes compared between pre- and post-intervention assessments. This is a non-randomized, open-label study, meaning neither patients nor surgeons are blinded to the treatment

Settings and conduct
Patients presenting with impaired bone healing will receive an injection of NMImETIC peptide nanofibers at the defect site at Omid Hospital or Dr. Mottalebizadeh's clinic. 1. Infection and pain intensity at 2 weeks 4 months follow-up: 2. Callus formation: AP and lateral radiographic projections 3. Quantitative evaluation: RUST Score 4. Delayed and Nonunion

Participants/Inclusion and exclusion criteria
Inclusion 1. Age: 18 to 70 years. 2. Gender: Both males and females. 3. Clinical history: Patients who underwent MTN surgery and exhibited 4. suboptimal bone healing at the 4-month post-operative follow-up. Compliance: Willingness to participate in and adhere to all phases of the study protocol. Exclusion Alcohol consumption. Pregnancy or lactation. Uncontrolled diabetes mellitus. Autoimmune or immunodeficiency disorders. Medical conditions that could interfere with study outcomes A history of intravenous bisphosphonate therapy. Malignancy (cancer) or current chemotherapy treatment. Conditions related to calcium malabsorption. Tobacco use

Intervention groups
In this study, NMImETIC Peptide Nanofibers will be used in individuals with leg length discrepancy who have not responded to bone repair.

Main outcome variables
Bone Regeneration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210526051407N3**
Registration date: **2026-10-30, 1405/08/08**
Registration timing: **prospective**

Last update: **2026-10-30, 1405/08/08**
Update count: **0**

Registration date
2026-10-30, 1405/08/08

Registrant information

Name
Shima Tavakol

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8670 4722

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Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2027-09-29, 1406/07/07

Expected recruitment end date
2027-09-29, 1406/07/07

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial study of bone repair product NMImETIC Peptide Nanofibers in Patients with Leg Length Discrepancy

Public title
Clinical trial study of bone repair product NMImETIC Peptide Nanofibers in Patients with Leg Length Discrepancy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age 18-70 year-old Men and women Patients who underwent MTN surgery and exhibited inadequate bone healing after a 4-month follow-up period Willingness to participate in all phases of the study Patient with Leg Length Discrepancy
Exclusion criteria:
Alcohol consumption Pregnancy or lactation Uncontrolled diabetes mellitus Autoimmune or immunodeficiency disorders Medical conditions that could interfere with study outcomes (e.g., neurological, psychiatric, or infectious diseases). Current use of oral bisphosphonates or a history of intravenous bisphosphonate therapy Malignancy (cancer) or current chemotherapy treatment. Conditions related to calcium malabsorption Tobacco use
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **6**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, next to Milad tower, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
14496145230
Approval date
2026-09-13, 1405/06/22
Ethics committee reference number
IR.IUMS.REC.1405.359

Health conditions studied

1

Description of health condition studied
Compromised bone regeneration
ICD-10 code
M84.36
ICD-10 code description
Stress fracture, tibia and fibula

Primary outcomes

1

Description
Bone regeneration
Timepoint
Before intervention and 4 months after intervention
Method of measurement
X-Ray

Secondary outcomes

1

Description
Pain and Infection
Timepoint
Before intervention and 2 weeks after intervention
Method of measurement
VAS and observationa

Intervention groups

1

Description
Intervention group: Single-dose percutaneous injection of NMImETIC Peptide Nanofibers bone-graft product (Tavakol BioMimetic Technologies Co) at the fracture site
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Nader Motalebizadeh Clinic

Full name of responsible person
Dr. Nader Motalebizadeh

Street address
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Email
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Web page address

2

Recruitment center

Name of recruitment center
Omid Hospital

Full name of responsible person
Dr. Nader Motalebizadeh

Street address
Tehran, Jannatabad Central, North Shahin St., Kabiri Tameh St., Bahar St, NO 15

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr. Majid Safa

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Web page address

Grant name

Grant code / Reference number
۱۴۰۴-۴-۲۰-۳۶۰۰۴

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
14

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
Tavakol BioMimetic Technologies

Full name of responsible person
Dr. Shima Tavakol

Street address
Tavakol BioMimetic Technologies Company, Iranian Research Organization for Science and Technology, Ahmad Abad-E- Mostovfi, Tehran

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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
Tavakol BioMimetic Technologies

Proportion provided by this source
86

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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Person responsible for scientific inquiries

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Name of organization / entity
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Other areas of specialty/work
Medical Nanotechnology

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Person responsible for updating data

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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
Yes - There is 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
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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Published paper

When the data will become available and for how long
3 months after paper publication

To whom data/document is available
Published paper will be available for all groups

Under which criteria data/document could be used
Only published paper will be available.

From where data/document is obtainable
published paper

What processes are involved for a request to access data/document
published paper

Comments