Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Phase II clinical trial on effectiveness of synthetic bilayer scaffold composed of amniotic membrane and silk fibroin in Wagner ulcers II in comparison with amniotic membrane

Protocol summary

Summary

The aim of the present study is to investigate the effectiveness of the synthetic bilayer scaffold in comparison with amniotic membrane as a wound dressing in healing and reconstruction of chronic skin ulcers in diabetic patients, who did not respond to standard treatments over one month pre-intervention. The synthetic bilayer scaffold is fabricated by coating a layer of electrospun silk fibroin nanofibers on decellularized amniotic membrane. Participants in this clinical trial (phase II) include 20 diabetic patients, aged between 18 and 60 years old. The wound area must be between 1 to 20 square centimeter, the patients must have the wound for at least one month, and there must be no disruption in blood circulation to the wound site. In this clinical trial, two study and control groups are considered and 10 patients are studied from both genders in each group. A randomized, single-blind, parallel-group study is designed and participating patients are assigned according to random numbers table. Subjects are kept blind to treatment assignment. The synthetic bilayer scaffold and decellularized amniotic membrane are studied in study and control groups, respectively. The studying process includes the following steps: scaffold fabrication; obtaining informed consent and application of wound dressings; wound healing assessment on weekly and monthly basis by studying factors such as size and thickness, tensile and flexibility, smell and color, and vascularization.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071328903N1**
Registration date: **2016-12-27, 1395/10/07**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-12-27, 1395/10/07

Registrant information

Name

Shaghayegh Arasteh

Name of organization / entity

Avicenna Research Institute

Country

Iran (Islamic Republic of)

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s.arasteh@avicenna.ac.ir

Recruitment status

Recruitment complete

Funding source

Avicenna Research Institute Center for Research and Training in Skin Diseases and Leprosy

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-03-15, 1395/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Phase II clinical trial on effectiveness of synthetic bilayer scaffold composed of amniotic membrane and silk fibroin in Wagner ulcers II in comparison with amniotic membrane

Public title
Clinical evaluation of the efficacy of a novel wound dressing on treatment of wagner ulcer grade II
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: diagnosed with diabetes; within the age range of 18 to 60 years; wound area between 1 to 20 square centimeter; one month passed wound creation
Exclusion criteria: simultaneous wound infection (active cellulite, osteomyelitis, sinus infection, etc.); more than 50% wound healing in one month period prior to intervention; simultaneous diagnosis with metastatic diseases or malignant diseases, especially those involving hematologic system or bone; receiving chemotherapy or immunosuppressive medications; simultaneous diagnosis with an autoimmune disease such as chronic lymphocytic thyroiditis, arthritis rheumatoid, and lupus; administration of therapeutic agents containing growth factors; hemoglobin level of less than 10 mg/dl or thrombocytopenia (platelets of less than 100,000); serum albumin level of less than 2.5 g/dl; records of vascular surgery in 3 months period prior to intervention; addiction to oral or injectable narcotic drugs; diagnosis with any systemic disease which would interfere with the process of wound healing; pregnancy, breastfeeding; history of vascular disorders or neuropathy; history of diagnosis with hematologic disorders; diagnosis with any conditions requiring treatment such as gangrene; application of injectable, oral antibiotic in 48 hours prior to intervention; patient participation in other clinical trials in three months pre-intervention; no disruption in blood circulation to the wounded region
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Tehran University of Medical Sciences
Street address
University Research Ethics Committee, Research Affairs Management, University Research Chancellor, Number 23, Dameshgh Ave, Felestin Ave, Keshavarz Boulevard
City
Tehran
Postal code
Approval date
2016-07-09, 1395/04/19
Ethics committee reference number
IR.TUMS.REC.1395.2758

Health conditions studied

1

Description of health condition studied
Wagner ulcer grade II
ICD-10 code
E14
ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Wound dimension
Timepoint
Before intervention and after intervention on days 7, 14, 30, 45 and 60
Method of measurement
Caliper

2

Description
Wound colour
Timepoint
Before intervention and after intervention on days 7, 14, 30, 45 and 60
Method of measurement
Dermaspectrometer, chromameter and observer

3

Description
Biomechanical properties
Timepoint
After intervention on days 7, 14, 30, 45 and 60
Method of measurement
Tensile testing

4

Description
Wound surface properties
Timepoint
After intervention on days 7, 14, 30, 45 and 60
Method of measurement
Three-dimensional optical profiling system

Secondary outcomes

1

Description
Tissue healing
Timepoint
Sixty days after intervention
Method of measurement
Hematoxylin and eosin staining

2

Description
Quality assessment of involucrin
Timepoint
Sixty days after intervention
Method of measurement
Involucrin immunohistochemical staining

3

Description
Tissue reconstruction
Timepoint
Sixty days after intervention
Method of measurement
Masson's trichrome staining

4

Description
Quality assessment of collagen
Timepoint
Sixty days after intervention
Method of measurement
Collagen immunohistochemical staining

5

Description
Quality assessment of p63
Timepoint
Sixty days after intervention
Method of measurement
P63 immunohistochemical staining

Intervention groups

1

Description
In intervention group, the bilayer scaffold is used as a wound dressing and is changed once a week over a 6-weeks period. The bilayer scaffold is based on amniotic membrane and silk fibroin and is fabricated by coating a layer of electrospun silk fibroin nanofibers on decellularized amniotic membrane.
Category
Treatment - Other

2

Description
In control group, decellularized amniotic membrane is used as a wound dressing and is changed once a week over a 6-weeks period.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Center for Research and Training in Skin Diseases and Leprosy
Full name of responsible person
Dr Zeinab Variji
Street address
No. 415, Junction of Shahid Naderi Ave., Taleqani Ave.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology of Avicenna Research Institute
Full name of responsible person
Dr MohammadReza Sadeghi
Street address
Third Floor, Avicenna Research Institute, Shahid Beheshti University, Daneshjou Boulevard, Shahid Shahriari Square, Yaman Avenue, Shahid Chamran Highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research and Technology of Avicenna Research Institute
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Center for Research and Training in Skin Diseases and Leprosy

Full name of responsible person

Dr Ali Khamesipour

Street address

No. 415, Junction of Shahid Naderi Ave., Taleqani Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Center for Research and Training in Skin Diseases and Leprosy

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Center for Research and Training in Skin Diseases and Leprosy

Full name of responsible person

Dr Alireza Firooz

Position

Professional Doctorate / Head of Center for Research and Training in Skin Diseases and Leprosy

Other areas of specialty/work

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Person responsible for scientific inquiries

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Dr Somaieh Kazemnejad

Position

PhD in Biochemical Biochemistry

Other areas of specialty/work

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Reproductive Biotechnology Research Center, Avicenna Research Institute, Shahid Beheshti University, Daneshjou Boulevard, Shahid Shahriari Square, Yaman Avenue, Shahid Chamran Highway

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Research Assistant / Master of Philosophy

Other areas of specialty/work

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Reproductive Biotechnology Research Center, Avicenna Research Institute, Shahid Beheshti University, Daneshjou Boulevard, Shahid Shahriari Square, Yaman Avenue, Shahid Chamran Highway

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty