

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)

Phone

+98 21 2243 2020

Email address

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

Street address

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

City

Tehran

Postal code

1416613675

Phone

+98 21 8897 8190

Fax

Email

firozali@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Avicenna Research Institute

Full name of responsible person

Dr Somaieh Kazemnejad

Position

PhD in Biochemical Biochemistry

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

1936773493

Phone

+98 21 2243 2020

Fax

Email

s.kazemnejad@ari.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Avicenna Research Institute

Full name of responsible person

Shaghayegh Arasteh

Position

Research Assistant / Master of Philosophy

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

1936773493

Phone

+98 21 2243 2020

Fax

Email

shaghayegh.ar@gmail.com; s.arasteh@ari.ir

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