

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The evaluation of tissue-engineered adipose-derived mesenchymal stem cells for wound healing in diabetes

Protocol summary

Study aim

This study aims to evaluate the effect of amniotic membrane and amniotic membrane seeded with stem cells on healing and closure time of chronic wounds. Actually, providing a tissue-engineered product using amniotic membrane as a scaffold and adipose tissue-derived mesenchymal stem cells for healing of diabetic ulcers will be investigated by the present study.

Design

This is a phase I and II clinical trial interventional study. Regardless of gender, people with the age of 15-45 were selected. The total of 32 patients have been considered as the study sample size and randomly interred to the determined groups.

Settings and conduct

The present study is conducted in the diabetes clinic 1-endocrinology and metabolism research institute. The evaluation of wound closure levels is performed on days 7-14-21 using photographic analyzes and Image J software has been used for data analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Signature of informed consent, Grade 1 or 2 wound on the Wagner scale, With a diagnosis of diabetic or other chronic wounds, Female or male patient aged 15-45 Not pregnant

Intervention groups

1- Intervention group: placenta scaffold 2- Intervention group: placenta scaffold containing stem cell 3- Intervention group: Adipose tissue derived stem cells 4- Control group: Dressing

Main outcome variables

Primary Outcome Measures: Ulcer Healing Rate
Secondary Outcome Measures: Time to ulcer healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191007045008N1**

Registration date: **2020-01-17, 1398/10/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-17, 1398/10/27**

Update count: **0**

Registration date

2020-01-17, 1398/10/27

Registrant information

Name

babak arjmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8835 4367

Email address

barjmand@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-12, 1398/07/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of tissue-engineered adipose-derived mesenchymal stem cells for wound healing in diabetes

Public title

Cell Therapy in wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Signature of informed consent Grade 1 or 2 wound on the Wagner Scale With diagnosis of diabetic or other chronic wound Female or male patient aged 15-45 Not pregnant

Exclusion criteria:

Patients with a history of uncontrolled disease Pregnancy Subjects with cancerous or pre-cancerous lesions in the area to be treated Patient with working activity who cannot be on sick-leave during the study period Known immunosuppressive disease, e.g. HIV infection, or hepatitis B or C infection

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences Endocrine & Metabolism Research Institute Ethics Committee

Street address

No.111,19th st., North Kargar Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

14579-65597

Approval date

2017-08-23, 1396/06/01

Ethics committee reference number

IR.tums.emri.rec.1396.00193

Health conditions studied

1

Description of health condition studied

diabetes mellitus type 1

ICD-10 code

E10.621

ICD-10 code description

Type 1 diabetes mellitus with ulcer

Primary outcomes

1

Description

Ulcer Healing Rate

Timepoint

7-14-21

Method of measurement

Ulcer Surface Area Measurement Using Instant Full-Scale Photography and analysis using Image J

Secondary outcomes

1

Description

Time to ulcer healing

Timepoint

7-14-21

Method of measurement

Instant full scale photography and analysis using Image J

Intervention groups

1

Description

Intervention group: placenta scaffold containing stem cell

Category

Treatment - Drugs

2

Description

Intervention group: placenta scaffold

Category

Treatment - Drugs

3

Description

Intervention group: Adipose tissue derived stem cells

Category

Treatment - Drugs

4

Description

Control group: Dressing

Category
Treatment - Devices

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetes Clinic
Full name of responsible person
Dr. Ensieh Nasli-Esfahani
Street address
No.111, 19th st., North Kargar Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14579-65597
Phone
+98 21 8835 4367
Email
barjmand@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
ندا مهرداد
Street address
No.111,19th st., North Kargar Ave., Tehran, Iran
City
tehran
Province
Tehran
Postal code
14579-65597
Phone
+98 21 8835 4367
Email
barjmand@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Babak Arjmand
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Others
Street address
No.111,19th St., North Kargar Ave., Tehran, Iran
City
tehran
Province
Tehran
Postal code
14579-65597
Phone
+98 21 8835 4367
Email
barjmand@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hamid Reza Aghayan
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Stem cell research, manufacturing and therapy
Street address
No.111, 19th St., North Kargar Ave., Tehran, Iran
City
tehran
Province
Tehran
Postal code
14579-65597
Phone
+98 21 8835 4367
Email
hr.aghayan@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person

Babak Arjmand

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

Street address

No.111,19th St., North Kargar Ave., Tehran, Iran

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Province

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Phone

+98 21 8835 4367

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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 data

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available