Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 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

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
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14579-65597
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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
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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
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
Type of organization providing the funding
Academic

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
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Contact
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Tehran University of Medical Sciences
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Hamid Reza Aghayan
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Stem cell research, manufacturing and therapy
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Full name of responsible person

Babak Arjmand

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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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