Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of a scaffold containing human placenta-derived mesenchymal stem cells in diabetic chronic wounds healing (phase II)

Protocol summary

Study aim
Investigation of the effect of a bandage containing stem cells derived from human-paired tissue on chronic wound healing in diabetic patients

Design
This is a phase 2 clinical trial intervention study. Regardless of gender, individuals between the ages of 18 and 45 will be selected. A sample size of 30 individuals has been considered and will be randomly assigned to the designated groups. Entry criteria: Informed consent for the treatment of grade 1 or 2 wounds with a diagnosis of diabetes and no pregnancy. Exit criteria: patients with uncontrolled disease history, pregnant individuals, and individuals with cancerous or pre-cancerous lesions in the treated area.

Settings and conduct
On the day of transplantation, an appropriate number of AAM, AMM+PLMSC, and PLMSC will be transferred to the clinic. During the transplantation, continuous monitoring of vital signs (heart rate, oxygen saturation, heart rhythm, and blood pressure) and any undesirable signs will be performed.

Participants/Inclusion and exclusion criteria
Informed consent for the treatment of grade 1 or 2 wounds with a diagnosis of diabetes and no pregnancy. Exit criteria: patients with uncontrolled disease history, pregnant individuals, and individuals with cancerous or pre-cancerous lesions in the treated area.

Intervention groups
AAM; PLMSCs + AAM; Ctrl

Main outcome variables
Wound closure rate- Tissue regeneration- Inflammatory response- Pain reduction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191007045008N2**
Registration date: **2023-07-26, 1402/05/04**
Registration timing: **prospective**

Last update: **2023-07-26, 1402/05/04**
Update count: **0**

Registration date
2023-07-26, 1402/05/04

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
2023-09-06, 1402/06/15

Expected recruitment end date
2025-03-20, 1403/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of a scaffold containing human placenta-derived mesenchymal stem cells in diabetic chronic wounds healing (phase II)

Public title

stem cells for diabetic chronic wounds healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Sign Informed consent form Diagnosed with diabetes mellitus no pregnancy grade 1 or 2 wounds Men or women, 18 years old and above

Exclusion criteria:

uncontrolled disease history pregnancy cancerous or pre-cancerous lesions in the treated area

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will use a randomized, double-blind design to investigate the effect of AAM and PLMSCs on wound healing in diabetic patients. Participants will be randomly assigned to one of three groups: AAM group, PLMSCs + AAM group, or control group. The AAM group will receive a scaffold containing an acellular amniotic membrane, the PLMSCs + AAM group will receive a scaffold containing both placenta-derived mesenchymal stem cells and acellular amniotic membrane, and the control group will receive a placebo scaffold without any active ingredients. Randomization will be performed using a computer-generated randomization list that will be created by an independent statistician. The randomization list will be stratified by age, gender, and wound size to ensure a balance between the three groups. The study investigators, participants, and outcome assessors will be blinded to treatment allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

To maintain blinding, all study scaffolds will be identical in appearance and packaging. The study investigators will not know which scaffold each participant receives. The outcome assessors will also be blinded to treatment allocation and will not know which group each participant belongs to when assessing wound healing outcomes. In addition, participants will be instructed not to reveal their treatment allocation to the outcome assessors during follow-up visits. Any unblinding events will be recorded and reported in the study findings.

Placebo

Not 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

2023-04-15, 1402/01/26

Ethics committee reference number

IR.TUMS.EMRI.REC.1402.010

Health conditions studied

1

Description of health condition studied

diabetes mellitus

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Percentage of wound closure

Timepoint

several weeks to several months

Method of measurement

It will be measured using digital photography and software analysis

Secondary outcomes

1

Description

time to complete wound closure

Timepoint

vary from weeks to months

Method of measurement

digital photography and software analysis

2

Description
pain reduction
Timepoint
several weeks
Method of measurement
visual analog scale

3

Description
quality of life improvement
Timepoint
several months to several years
Method of measurement
validated questionnaire

Intervention groups

1

Description
Intervention group 1: AAM (Acellular amniotic membrane) Amniotic membrane preparation: The acellular amniotic membrane were used to providing the three-dimensional scaffold for seeding MSCs. After obtaining informed consent placenta was donated from healthy mother after caesarean delivery. placenta rinsed in sterile (PBS) and then human amniotic membrane(HAM) was separated from the chorion with forceps and washed three times with PBScontaining Penicillin-Streptomycin (10,000 U/mL)(gibco, usa) and cut into 3 cm×3 cm pieces, which were placed in dishes with the amniotic epithelial layer face up. Then pieces of HAM were decellularized with 0.5 M NaOH according to previous study(Saghizadeh, Winkler et al. 2013). all the procedures were carried out under aseptic conditions. haematoxylin and eosin (H&E) staining of the samples were accomplished to confirme Aecellularization process. Samples were viewed by light microscopy after staining with H&E. On the desired day for transplantation, membranes and tissue engineering products are transported to the hospital by Cool Box, and in this group, the acellularized amnion membrane is placed on the wound site. After 6 weeks, the final result will be seen. Of course, during this period, the healing process of the wound will be checked once a week.
Category
Treatment - Devices

2

Description
Intervention group 2: AAM+PLMSCs (acellular human amniotic membrane graft+placenta-derived MSCs). Mesenchymal stem cells are counted and suspended in fresh culture media. In each piece, 3 ml of cell suspension is planted and incubated at 37°C, 5% CO2 and 95% humidity. After 24 hours, the culture medium is changed. On the fifth day, the prepared tissue engineered grafts will be ready for transplantation. The grafts are packed in sterile bottles and transported to the clinic for transplantation. Grafts are transplanted to the wound site for 6 weeks, this transplant will be done once a week, and after 6 weeks the results will be evaluated. Patients will be followed up weekly for the first month and then monthly for 6 months.
Category
Treatment - Devices

3

Description
Control group: Ctrl (will receive a normal 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Neda Mehrdad
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Email
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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

50

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Babak Arjmand

Position

Associated Professor

Latest degree

Ph.D.

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Babak Arjmand

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Babak Arjmand

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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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

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable