

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the efficacy of lyophilized human amniotic membrane as a dressing on chronic diabetic foot wound healing

Protocol summary

Study aim

determination of efficiency of lyophilized human amniotic membrane
determination of duration of wound healing using lyophilized human amniotic membrane
determination of size alteration of the ulcer
determination of improvement of appearance of the ulcer

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Bu ali hospital, Two arm parallel study, In this study block randomization generated by an online tool (<https://www.sealedenvelope.com/simple-randomiser/v1/ist>) . This tool was used to assign patients to the treatment and the control group.

Participants/Inclusion and exclusion criteria

Inclusion: Diabetic patients with chronic wound for which other treatment were effectlessness. Exclusion: Patients with infectious wounds due to possible proliferative effect of amniotic membrane which can worsen the infection.

Intervention groups

Diabetic patients with chronic wound for which other treatment were effectlessness. patients will be randomly divided into two groups; in intervention group we use hydrogel containing human lyophilized amniotic membrane after cleaning and debridement of the wound. in control group we only clean and debride the wound.

Main outcome variables

ulcer size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190131042570N1**

Registration date: **2019-12-28, 1398/10/07**

Registration timing: **prospective**

Last update: **2019-12-28, 1398/10/07**

Update count: **0**

Registration date

2019-12-28, 1398/10/07

Registrant information

Name

aida rezaei nejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2229 1287

Email address

aidarezaeen@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-10, 1398/10/20

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of lyophilized human amniotic membrane as a dressing on chronic diabetic foot wound healing

Public title

Lyophilized human amniotic membrane; a dressing for chronic diabetic foot wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patient with chronic diabetic foot HbA1C<8 ulcer
duration less than one year having dorsalis pedis and
posterior tibialis pulses Ulcer size ≥ 1 cm² and < 25 cm²
No clinical signs of infection

Exclusion criteria:

other therapies in the last three months
immunocompromised patient patients with history of
allergy or hemostasis disorders Pregnant or breast
feeding received corticosteroids or immunosuppressive
drugs in the last six months smoking cigarette Known or
suspected malignancy of current ulcer

Age

From **35 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study block randomization generated by an online
tool
(<https://www.sealedenvelope.com/simple-randomiser/v1/ist>) . This tool was used to assign patients to the
treatment and the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study the products (with and without amniotic
membrane) which have the same appearance will be
applied by an expert nurse who does not know the group
assignment. The wounds will be evaluated by two
physicians who do not know the group assignment.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran islamic azad university of medical science =

Street address

13th Flr., Block A, Central HQs of the Ministry of
Health & Medical Education, Simaye_Iran St., Qods

Town

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2018-09-03, 1397/06/12

Ethics committee reference number

IR.IAU.TMU.REC.1397.145

Health conditions studied**1****Description of health condition studied**

Diabetic foot ulcer

ICD-10 code

621

ICD-10 code description

E11

Primary outcomes**1****Description**

ulcer size

Timepoint

at baseline, in 1 week, 2 weeks, 4 weeks and 6 weeks

Method of measurement

by ruler

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: hydro-gel containing lyophilized
human amniotic membrane, dress every 2 or 3 days, 3 or
4 times

Category

Treatment - Drugs

2**Description**

Control group: sterilized hydro-gel, dress every 2 or 3
days, 3 or 4 times

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu ali Hospital

Full name of responsible person

Zahra Sadeghi

Street address

Buali hospital, Damavand St., Imam Hussein squire

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1711734353

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na@na.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Stem Cell and Regenerative Medicine Research Center

Full name of responsible person

Mohammad Amir Amirkhani

Street address

stem cell and regenerative medicine research center, italia Str. , keshavarz Blv, Tehran

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amirkhani@health.gov.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Tehran Medical University

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

The Stem Cell and Regenerative Medicine Research Center

Full name of responsible person

Aida Rezaei Nejad

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

The stem cell and regenerative medicine research center

Full name of responsible person

Mohammad Amir Amirkhani

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

The Stem Cell and Regenerative Medicine Research

Center

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Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

demographic characteristic, clinical and para clinical data
before and after study

When the data will become available and for how long

after publishing paper

To whom data/document is available

researchers

Under which criteria data/document could be used

explain about their study

From where data/document is obtainable

corresponding or first author

What processes are involved for a request to access data/document

email

Comments