Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 hosptal, Two arm parallel study, In this study block randomization generated by an online tool (https://www.sealedenvelope.com/simple-randomiser/v1/list) . 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 effectless. Exclusion: Patients with infectious wounds due to possible prolifirative effect of amniotic membrane which can worsen the infection.

Intervention groups
Diabetic patients with chronic wound for which other treatment were effectless. patients will be randomly divided into two groups; in intervention group we use hygrogel 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 immunosuppresive 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/list) . 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 F̈lr., Block A, Central HQ̈s of the Ministry of Health & Medical Education, Simaye_Iran St., Qods Town

City
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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Stem Cell and Regenerative Medicine Research Center

Full name of responsible person
Mohammad Amir Amirkhani

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

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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

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Person responsible for updating data

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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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