

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Safety evaluation of amniotic membrane extract in management of the diabetic foot ulcers

Protocol summary

Study aim

- reduction of wound size and the proportion of ulcers completely healed after 4 and 6 weeks
- the reduction time of wound size $\leq 50\%$
- the safety amniotic membrane extract
- not formation of tissues fibrosis and necrosis

Design

clinical trial, controlled

Settings and conduct

All the patients enrolled in the study will be interviewed and the study will be explained for them. If patients agree with study they should read and sign an approved informed consent form prior to enrollment. Basic information related to each patient will be registered .this information contains : General condition of health, age, sex, weight, systemic diseases, duration of diabetic wound, location of ulcer, size of ulcer, degree of destruction and presence or absence of infection. This study is done at Firoozgar Hospital and the Royan Diabetes Prevention Clinic

Participants/Inclusion and exclusion criteria

Inclusion Criteria Age 18 or older Ulcer duration of ≥ 4 weeks No clinical signs of infection : Pregnant or breast feeding; exclusion Criteria Sensitivity to drug uses Smoking and drug abuse

Intervention groups

Diabetic foot ulcer Patients

Main outcome variables

- Gender
- Age (years)
- Ulcer location
- Baseline wound size(cm²)
- Time to healing with AME
- Adverse event

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180102038195N1**

Registration date: **2018-08-16, 1397/05/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-16, 1397/05/25**

Update count: **0**

Registration date

2018-08-16, 1397/05/25

Registrant information

Name

Mohammad Azimi alamouty

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2233 9913

Email address

m_azimi67@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-25, 1397/05/03

Expected recruitment end date

2018-08-25, 1397/06/03

Actual recruitment start date

2017-07-25, 1396/05/03

Actual recruitment end date

2018-08-25, 1397/06/03

Trial completion date

empty

Scientific title

Safety evaluation of amniotic membrane extract in management of the diabetic foot ulcers

Public title

Safety evaluation of amniotic membrane extract in management of the diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 or older To be able and willing to provide consent letter and agree to comply with study procedures and follow-up evaluations Ulcer size >1 and <36 cm² Ulcer duration of ≥4 weeks No clinical signs of infection Serum creatinine <3 mg/dl Glycosylated haemoglobin (HbA1c) <12% Adequate circulation Ankle-brachial index (ABI) between 0.7 and 1.2 or having a normal Doppler arterial

Exclusion criteria:

participating in another clinical trial Currently receiving radiation or chemotherapy known or suspected malignancy of current ulcer Diagnosis of autoimmune connective tissue disease Received a biomedical or topical growth factor for their wound within the previous 30 days Pregnant or breast feeding Sensitivity to drug uses Smoking and drug abuse

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Actual sample size reached: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

not

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Royan institute

Street address

Royan Research Institute, East Hafez Alley, Royan St ,
Bani Hashem Street, Resalat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

148- 16635

Approval date

2017-08-25, 1396/06/03

Ethics committee reference number

1396.63.IR.ACECR.ROYAN.REC

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Side effectes

Timepoint

Every week

Method of measurement

Common Terminology Criteria for Adverse Events

2

Description

Wound healing rate

Timepoint

Every week

Method of measurement

AutoCAD software

Secondary outcomes

empty

Intervention groups

1

Description

Use of amniotic membrane extract in the treatment of diabetic foot ulcers

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Mahin Jamshidi

Street address

Firoozgar educational research center, Zahid Valadi
Street, Vali Asr Square, Tehran, IRAN

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Marzieh Ebrahimi
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Royan Research Institute, East Hafez Alley, Royan St, Bani Hashem Street, Resalat Highway, Tehran
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http://www.royaninstitute.org/cmsfa/index.php?option=com_frontpage&Itemid=1

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranian academic center for education culture and research

Proportion provided by this source

100

Public or private sector

Private

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
Iran University of Medical Sciences
Full name of responsible person
Mahin Jamshidi
Position
Doctors Infectiologist
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Marzie Ebrahimi
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Latest degree
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Person responsible for updating data

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Mohammad Azimi

Position

دانشجوی دکتری

Latest degree

Master

Other areas of specialty/work

مهندسی بافت

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Web page address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

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

Title and more details about the data/document

• wound size and proportion reduction of ulcers completely healed after 4 and 6 weeks • the reduction time of wound size $\leq 50\%$ • the safety of amniotic membrane extract • no formation of fibrosis and necrosis tissues • Pain reduction • The rate of antibiotics taken during treatment

When the data will become available and for how long

6 months after the publication of results

To whom data/document is available

Only for researchers who are working in academic and scientific institutions

Under which criteria data/document could be used

In clinical Trail's

From where data/document is obtainable

Marzieh Ebrahimi Royan Research Institute, East Hafez Alley, Royan St, Bani Hashem Street, Resalat Highway, Tehran Work Phone: + 982122402486
mebrahimi@royaninstitute.org

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

sending an email

Comments

not