

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the Effect of Gel with Middle Amniotic Formulation in Healing Diabetic Foot Ulcers

Protocol summary

Study aim

1. Comparison Healing, Discharge, Color, Degree and Tissues Around Diabetic Foot Ulcers in Four Amniotic Fluid Bagel Treatment Groups in Doses of 20, 40 and 60% Before and After 8 Weeks of Intervention

Design

Clinical Trial with Control Group, with Parallel Groups, Three-Way Blind, Randomized, Phase 2 on 92 Patients. Block Method was Used for Randomization

Settings and conduct

Location: Ahvaz Golestan Hospital Diabetes Clinic and Ahvaz Neurogenic Laboratory Three-Blind Study: Researcher, Research Units and Wound Healing Evaluator (Physician) are not Aware of the Dressing dose. Method: Random Allocation of Individuals in Intervention and Control Groups; Examination and Washing of the Wound; Placing Three Dressings with Different Doses of Amniotic Fluid on the Wound Site in the Intervention Groups; Placebo Dressing (Containing all Gels Except Amniotic Fluid) in the Control Group

Participants/Inclusion and exclusion criteria

Inclusion Criteria: The Wound must be in the Foot Area, One Year has Passed Since the Wound was Created
Exclusion Criteria: Participant's Refusal to Continue Treatment

Intervention groups

Intervention Group 1: Use of Gel with Amniotic Fluid Formulation with 20% Intervention Group 2: Use of Gel with Amniotic Fluid Formulation with 40% Intervention Group 3: Use of Gel with Amniotic Fluid Formulation with 60% Control Group: Using a Placebo that Contains All of the Gel Except the Amniotic Fluid

Main outcome variables

An Effective Step Towards Healing Diabetic Foot Ulcers; Improve the Quality of Care Provided

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201010048985N1**
Registration date: **2020-11-18, 1399/08/28**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name

Fatemeh Niami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 6626 8868

Email address

fatiniami66@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-18, 1399/07/27

Expected recruitment end date

2020-12-17, 1399/09/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Gel with Middle Amniotic Formulation in Healing Diabetic Foot Ulcers

Public title

Effect of Gel with Middle Amniotic Formulation in Diabetic Foot Ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Since the Wound was Made has Passed More than a Year
The Wound Must be in the Foot Area

Exclusion criteria:

The wound is in an area except the foot

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: 92

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are divided into 4 equal groups by using random block method (8 blocks with equal volume) that will include three intervention groups and a control group. In the random method at first, the blocks are marked with labels A, B, C, D and then each person will be placed in one of the blocks.

Blinding (investigator's opinion)

Triple blinded

Blinding description

For blinding in this study, Gel with Amniotic Fluid Formulation will be produced by a pharmacologist in three doses of 20, 40 and 60 percent and placebo and the dose of drugs with labels A, B, C, D that only the pharmacologist is aware of their percentage and researchers, participants and data analysts are not aware of the type of intervention and amniotic fluid concentration.

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical

Sciences

Street address

No. 8, Golestan Blvd., Ahvaz Town

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Ahvaz

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Khuzestan

Postal code

6975116955

Approval date

2020-09-28, 1399/07/07

Ethics committee reference number

IR.AJUMS.REC.1399.516

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Healing Diabetic Foot Ulcers

Timepoint

From the Beginning of the Study Until 8 Weeks after the Start Date of the Intervention

Method of measurement

Use a Diabetic Foot Wound Healing Checklist

Secondary outcomes

1

Description

Diabetic Foot Wound Healing

Timepoint

From the Beginning of the Study until 8 Weeks after the Start Date of the Intervention

Method of measurement

Diabetic Foot Ulcer Checklist

2

Description

Diabetic Foot Ulcer Discharge

Timepoint

From the Beginning of the Study until 8 Weeks after the Start Date of the Intervention

Method of measurement

Diabetic Foot Ulcer Checklist

3

Description

Diabetic Foot Ulcer Around Tissues

Timepoint

From the Beginning of the Study until 8 Weeks after the

Start Date of the Intervention
Method of measurement
Diabetic Foot Ulcer Checklist

4

Description

Diabetic Foot Ulcer Color

Timepoint

From the Beginning of the Study until 8 Weeks after the Start Date of the Intervention

Method of measurement

Diabetic Foot Ulcer Checklist

5

Description

Diabetic Foot Ulcer Degree

Timepoint

From the Beginning of the Study until 8 Weeks after the Start Date of the Intervention

Method of measurement

Diabetic Foot Ulcer Checklist

Intervention groups

1

Description

First Intervention Group: Apply Amniotic Fluid Gel Dressing with a Concentration of 20% every 48 hours for 8 Weeks on Diabetic Foot Ulcers

Category

Treatment - Drugs

2

Description

Second Intervention Group: Apply Amniotic Fluid Gel Dressing with a Concentration of 40% every 48 hours for 8 Weeks on Diabetic Foot Ulcers

Category

Treatment - Drugs

3

Description

Third Intervention Group: Apply Amniotic Fluid Gel Dressing with a Concentration of 60% every 48 hours for 8 Weeks on Diabetic Foot Ulcers

Category

Treatment - Drugs

4

Description

Control Group: Apply Placebo Dressing every 48 hours for 8 Weeks on Diabetic Foot Ulcers

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital Diabetes Clinic

Full name of responsible person

Fatemeh Niami

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2

Recruitment center

Name of recruitment center

Neurogenic Laboratory

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehdi Ahmadi Moghadam

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Vice Chancellor for Research and Technology Development of Ahvaz Jundishapur University of Medical Sciences and Health Services - University City -Ahvaz

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ajums.ac.ir@gmail.com

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

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Niami

Position

Msc Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

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Latest degree

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Other areas of specialty/work

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Fax**Email**

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

Some Data such as dDemographic Information and Information about the Mmain Result in this Study can be Shared.

When the data will become available and for how long

Access Period Starts from 2021

To whom data/document is available

The Data will be Available to Researchers Working in Academic and Scientific Institutions

Under which criteria data/document could be used

Information after the Final Publication of the Article can

be Accessed by Sending an Email

From where data/document is obtainable

Send Email to the Response Author of the Article

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

Send Email to the Response Author of the Article

Comments