

# 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

#### City

Ahvaz

#### Province

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

**Street address**

No. 8, Golestan Blvd., Ahvaz Town

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**Postal code**

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**Phone**

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**2**

**Recruitment center**

**Name of recruitment center**

Neurogenic Laboratory

**Full name of responsible person**

Fatemeh Niami

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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

**Street address**

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

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**Province**

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**Phone**

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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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Shahram Molavi Nejad

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data****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

**Street address**

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**Phone**

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**Fax****Email**

fatiniami66@gmail.com

**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**