Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the healing effects of hydrogel dressing on non-infectious diabetic wounds: a pilot study

Protocol summary

Study aim

Considering the high prevalence of diabetic wounds and the inability of current dressings to meet the needs of patients and the expectations of doctors, the existence of an effective dressing that has a long-term durability and the ability to prevent re-infection of the wound is required

Design

The study is a pilot study and will be conducted on 20 volunteers with type 2 diabetes who have diabetic foot ulcers. The non-random sampling method is easy and people will be included in the study in order.

Settings and conduct

In order to conduct this pilot study, 20 human subjects with type 2 diabetes who have diabetic foot ulcers entered the study with written consent and completely voluntarily, and gelatin hydrogel dressing was applied to the wound which was completely clean and free of infection and in the stage of good granulation tissue. is located, is used.

Participants/Inclusion and exclusion criteria

Entry criteria: over 18 years old - suffering from a diabetic foot ulcer that is in good granulation tissue condition Exclusion criteria: having severe clinical conditions such as active cancer, chronic hepatitis, HIV, uncontrolled autoimmune diseases, platelet problems, thrombocytopenia, bone marrow aplasia, blood infection, osteomyelitis, mental problems, local or systemic treatments such as chemotherapy

Intervention groups

There is only one treatment group for which the intervention is processed in a way that the hydrogel is applied on the wound bed, and the final results will be evaluated on the base of research variables (including the recovery time, duration of hydrogel retention on the wound, protection of the wound surface, and protection of the moist surface) at intervals of 3 and 7 days

Main outcome variables

Absorption of secretions-Persistence on the wound-Protect the wound surface-Wet surface protection-Duration of relative recovery

General information

Reason for update

Acronym

hydrogel

IRCT registration information

IRCT registration number: **IRCT20240306061194N1**
Registration date: **2024-04-06, 1403/01/18**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-06, 1403/01/18**
Update count: **0**

Registration date

2024-04-06, 1403/01/18

Registrant information

Name

Hamid Solgi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2024-04-19, 1403/01/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the healing effects of hydrogel dressing on non-infectious diabetic wounds: a pilot study

Public title
Investigating the healing effects of hydrogel dressing on non-infectious diabetic wounds: a pilot study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic foot ulcer with good granulation tissue
Exclusion criteria:
Having serious clinical conditions such as active cancer, chronic hepatitis, HIV, uncontrolled autoimmune diseases, platelet problems, thrombocytopenia, bone marrow aplasia, blood infection, osteomyelitis, mental problems, local or systemic treatments such as chemotherapy, radiotherapy, and having wounds non-diabetic
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
Exclusion criteria: Any allergic reactions such as rash - Dissatisfaction with continued cooperation

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
thics committee of Isfahan University of Medical Sciences
Street address
medical university of Isfahan, Isfahan
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Province
Isfehan
Postal code
73461-81746
Approval date
2023-06-25, 1402/04/04
Ethics committee reference number
IR.ARI.MUI.REC.1402.041

Health conditions studied

1

Description of health condition studied
diabetic ulcer
ICD-10 code
E-11.9
ICD-10 code description
E-11.9

Primary outcomes

1

Description
Absorption of secretions-Persistence on the wound-Protect the wound surface-Wet surface protection-Duration of relative recovery
Timepoint
twice a week
Method of measurement
Visually and according to the doctor's opinion-Reduction in the size of the wound is determined quantitatively by measuring the wound size

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان خورشید-کلینیک دیابت سیاوش-کلینیک خانواده
Full name of responsible person
Dr. Mansour Siavash
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
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Dr.Mansour Siavash
Position
professor
Latest degree
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Person responsible for updating data

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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
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
The data related to the study variables will be published in the form of an article
When the data will become available and for how long
as the scientific paper is published
To whom data/document is available
All people
Under which criteria data/document could be used
No limitation
From where data/document is obtainable
Refer to the corresponding journal
What processes are involved for a request to access data/document
There is no limit to receiving data from the article
Comments