Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Efficacy of Topical Application of Honey Health Gel in Combination with Collagen on Diabetic Foot Ulcers in Patients Referring to Medical Centers

Protocol summary

Study aim
Determining the effectiveness of topical application of Hony Health gel in combination with collagen on wound infection in diabetic foot ulcer

Design
in this clinical trial,a controlled clinical trial was performed on 96 patients with a control group,a blind,placebo-controlled clinical trial

Settings and conduct
Background:Mashhad.Qaem &Imam Reza Hospitals &Khan-e-salamat clinic.the number of 96 studied groups is 3groups of 32that the control group received only routine hospital treatment.one of the intervention groups in addition to routine treatment,use Honey Health gel on the wound between once.the other group used Honey Health gel in combination with collagen(3 to 2 ratio)per day in the middle of the day. Single blind:the researcher 's help in the study of the wound condition,which is the type of intervention,collects information about the wound that is the condition of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness and consent to participate in the study and completion of the informed consent form Age between 18 and 60 years Absence of diseases such as leukemia Use of the same (identical) antibiotic among participants Diabetic foot wound infection of grade2,confirmed by an infectious disease specialist and based on IDSA Diabetes confirmed by an infectious disease specialist Wound size grade3according to the Bates–Jensen wound assessment tool Presence of only one diabetic foot ulcer Exclusion criteria: patient 's death no tendency to continue

Intervention groups
In the control group,routine hospital care will be used,which includes wound washing with normal saline and dressing with moist gauze.In one of the intervention groups,in addition to the standard method,Honey gel combined with collagen and In the other intervention group,Honey gel alone will be applied every other day for 28 days

Main outcome variables
Diabetic foot wound infections

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230916059439N2**
Registration date: **2026-01-21, 1404/11/01**
Registration timing: **registered_while_recruiting**

Last update: **2026-01-21, 1404/11/01**
Update count: **0**

Registration date
2026-01-21, 1404/11/01

Registrant information

Name
Reza Ghorbani Noghabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-21, 1404/11/01

Expected recruitment end date
2026-06-22, 1405/04/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Efficacy of Topical Application of Honey Health Gel in Combination with Collagen on Diabetic Foot Ulcers in Patients Referring to Medical Centers

Public title
The Efficacy of Topical Application of Honey Health Gel in Combination with Collagen on Diabetic Foot Ulcers
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness and consent to participate in the study and completion of the informed consent form Age between 18 and 60 years Absence of diseases such as leukemia and immunodeficiency Use of the same (identical) antibiotic among participants Diabetic foot wound infection of grade 2, confirmed by an infectious disease specialist and based on IDSA criteria Diabetes confirmed by an infectious disease specialist Wound size grade 3 according to the Bates–Jensen wound assessment tool Presence of only one diabetic foot ulcer
Exclusion criteria:
Patient death Unwillingness to continue participation during the study Occurrence of any disorder or specific condition during the study that precludes the use of Honey Health gel dressing in combination with collagen, such as concurrent use of any dressing other than the intervention dressing specified in this study Necessity of using any pharmacological or non-pharmacological intervention affecting diabetic foot wound infection Wound size grade 5 according to the Bates–Jensen wound assessment tool
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
the sampling method is based on the available method according to the criteria for entering the research . first , patients with type of diabetes that have the inclusion criteria in the study will be selected by available method and then randomly assigned to the three groups by using the three permutation blocks (ABC, CAB, BAC) . the choice of blocks is done randomly using dice throwing to sufficient sample size (96 people) . the samples that were selected by available sampling were selected according to the selected blocks in group A for the intervention of Honey Health Gel and B for the combination of Honey Health Gel with collagen and C for control .
Blinding (investigator's opinion)
Single blinded
Blinding description
prior to the study , informed consent of the company to participate in the study and eventual inclusion in one of the study groups (randomly) will be obtained . according to the method of random allocation that was mentioned in the sampling method , the patient was placed in group a or b or c . moreover , the researcher has trained the information about the wound that is without any knowledge about the wound condition .
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Gonabad University of Medical Sciences
Street address
Research and Technology Vice-Chancellor of Gonabad University of Medical Sciences,near Asian Road, Gonabad, Khorasan Razavi
City
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Province
Razavi Khorasan
Postal code
9691793718
Approval date
2025-12-29, 1404/10/08
Ethics committee reference number
IR.GMU.REC.1404.120

Health conditions studied

1

Description of health condition studied
Diabetic foot wound infection
ICD-10 code
L08.9
ICD-10 code description
Local infection of the skin and subcutaneous tissue, unspecified

Primary outcomes

1

Description
Diabetic foot wound infection
Timepoint
Before the intervention and immediately after the intervention
Method of measurement
IDSA tool and Bates-Jensen tool

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: n addition to the standard method, Honey Health gel combined with collagen will be applied every other day and once every turn for 28 days. The intervention involves placing a layer of Honey Health gel mixed with collagen on the wound after cleaning and washing the wound, which will then be covered with a layer of gauze. In other words, Honey Health gel and collagen powder are mixed at a ratio of 3:2 on a sterile surface, and the resulting mixture is applied evenly on the wound using sterile forceps, and finally covered with a layer of gauze. Producers: Pars Takrokh and Treatta pharmaceutical company
Category
N/A

2

Description
Intervention group: In addition to the standard method, Honey Health gel alone will be applied every other day and once every turn for 28 days. The intervention involves placing a layer of Honey Health gel on the wound after cleaning and washing the wound, which will then be covered with a layer of gauze. Producer: Pars Takrokh pharmaceutical company
Category
N/A

3

Description
Control group: In the control group, the routine hospital care method will be used, which includes wound washing with normal saline and dressing with moist gauze.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Educational Research and Treatment Center
Full name of responsible person
Reza Ghorbani Noughabi
Street address
Mashhad, Dr. Ali Shariati Square, beginning of Ahmadabad Street
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2

Recruitment center
Name of recruitment center
Imam Reza (AS) Educational, Research and Treatment Center
Full name of responsible person
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3

Recruitment center
Name of recruitment center
Aseman-e-Sharg Health Home Clinic
Full name of responsible person
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Dr. Beheshti Street, between Dr. Beheshti 16 and 18, Sasan Physicians Building
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Aseman-e-Sharg Health Home Company
Full name of responsible person
Saeed Abbasnezhad
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Khorasan Razavi Province, Mashhad County, Central District, Mashhad City, Koohsangi, Shahid Beheshti 9, Koohsangi 2, Kala-ye Tab-e Parastar and Aseman-e-Sharg Health Home Company
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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
Aseman-e-Sharg Health Home Company
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
Industry

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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

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