Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of healing rate of diabetic foot ulcer between two groups of dressing with ointment containing turmeric root extract and dressing with placebo in diabetic patients

Protocol summary

Study aim
Determining the healing rate of diabetic foot ulcer between two groups of dressing with ointment containing turmeric root extract and dressing with placebo in diabetic patients

Design
A controlled, parallel-group, triple-blind, randomized, phase 2-3 clinical trial on 72 patients. Randomized Block Design method was used for randomization.

Settings and conduct
Samples will be searched from patients who were admitted to Isfahan medical centers with complaints of diabetic foot ulcers. Participants in the groups were recorded and recorded by an independent researcher in a sealed envelope. In the diabetic foot wound dressing group with placebo ointment the placebo ointment, which is filled with Eucerin, will be used on the wound and then bandaged. In the dressing group with curcumin ointment, the diabetic foot wound will be dressed once a day using an ointment containing turmeric extract. During the physical examination, the area and depth of the wound will be measured and recorded daily.

Participants/Inclusion and exclusion criteria
Patients with type 2 diabetes with grade 1, 2, or 3 diabetic foot ulcers with consent to participate in the study, who have not used other treatment methods, are not heavy smokers, and do not have morbid obesity or vascular insufficiency.

Intervention groups
In the diabetic foot wound dressing group with placebo ointment, after usual washing with normal saline and routine treatment based on the TIME model, placebo ointment, which is completely similar to curcumin ointment in appearance, but filled with eucerin, will be used on the wound and then bandaged. . Eucerin's main topical product is a moisturizer. In the dressing group with curcumin ointment, the diabetic foot wound will be dressed once a day by a wound expert after washing with normal saline using an ointment containing turmeric root extract (so as to cover the wound).

Main outcome variables
Wound grading

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240927063181N1**
Registration date: **2024-09-29, 1403/07/08**
Registration timing: **prospective**

Last update: **2024-09-29, 1403/07/08**
Update count: **0**

Registration date
2024-09-29, 1403/07/08

Registrant information

Name
Gholamali Hoghooghi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-01, 1403/07/10

Expected recruitment end date
2024-11-20, 1403/08/30

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

Scientific title
Comparison of healing rate of diabetic foot ulcer between two groups of dressing with ointment containing turmeric root extract and dressing with placebo in diabetic patients

Public title
Comparison of healing rate of diabetic foot ulcer between two groups of dressing with ointment containing turmeric root extract and dressing with placebo in diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Type 2 diabetes Diabetic foot ulcer grade 3 or lower (grades 1, 2 and 3) according to "Wagner-Meggitt's" criteria Informed consent to participate in the study
Exclusion criteria:
Using other methods of treating diabetic foot ulcers, such as leech therapy, etc Heavy smoker patients Patients with morbid obesity (BMI>40) Patients with vascular insufficiency
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
This stage will be Randomized Block Design. At this stage, patients will be divided into 2 blocks (36 blocks of 2). Then they are sorted according to the national code (the larger national code of the first row of the block and the smaller national code of the second row of the block). After that, we refer to the table of random numbers for each block. If the selected number was from 0 to 4, the patient in the first row will join group A and the patient in the second row will join group B. If the selected number was from 5 to 9, the patient in the first row will join group B and the patient in the second row will join group A. After 36 patients in group A and 36 patients in group B are determined, the clinical pharmacologist, who is blinded to the selected patients, determines which group each of groups A and B will receive curcumin ointment or dressing. be with placebo ointment.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The placebo ointment looks exactly like the curcumin ointment, but it is filled with eucerin. Therefore, the researcher, the patient, and the data analyst are not aware of the type of ointment used, and only the data collector who is a trained clinical caregiver is aware of it.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Hezar Jerib St.sfahan University of Medical Sciences and Health Services, Building No. 4
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-12-26, 1402/10/05
Ethics committee reference number
IR.MUI.MED.REC.1402.358

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer
ICD-10 code
Z86.31
ICD-10 code description
Personal history of diabetic foot ulcer

Primary outcomes

1

Description
Grading of diabetic foot ulcers
Timepoint
The end of the first and second weeks after the start of treatment
Method of measurement

"Wagner-Meggitt's" criteria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the dressing group with curcumin ointment, the diabetic foot wound will be dressed once a day by a wound expert after washing with normal saline using an ointment containing turmeric root extract (so as to cover the wound).
Category
Treatment - Drugs

2

Description
Control group: In the diabetic foot wound dressing group with placebo ointment, after usual washing with normal saline and routine treatment based on the TIME model, placebo ointment, which is completely similar to curcumin ointment in appearance, but filled with eucerin, will be used on the wound and then bandaged. Eucerin's main topical product is a moisturizer that contains petrolatum, lanolin, mineral oil, and dimethicone as primary emollients, and glycerin, lecithin, and propylene glycol as secondary moisturizers.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Gholamali Hoghooghi
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Alzahra Hospital, Sofeh Blvd.
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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
Full name of responsible person
Gholamali Hoghooghi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Infectious diseases
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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Information is kept confidential.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
Yes - There is 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
Not applicable

Title and more details about the data/document
Information about the main outcome can be shared

When the data will become available and for how long
After publishing the results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Using data to complete studies

From where data/document is obtainable
Dr. Gholamali Hoghooghi, Isfahan University of Medical Sciences

What processes are involved for a request to access data/document
By examining the researcher's request and providing sufficient documentation of his research and the reason for using the data can be provided

Comments