Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effectiveness of the extract of the case compared to the conventional treatment (according to the protocol) in the treatment of diabetic foot ulcers after cutting in patients referred to Shahid Beheshti Hospital in Qom in 2023

Protocol summary

Study aim

Efficacy of using case extract compared to conventional treatment of diabetic foot ulcer after primary incision

Design

A clinical trial with a control group that is randomized in a block-randomized manner (1-blind intervention), randomized, on 40 patients (20 patients in each group) using a randomized block list that will be prepared using R software. , people will be assigned to each of the treatment groups.

Settings and conduct

The population of patients with diabetic foot ulcers who underwent debridement is washed 3 times a day for 8 weeks according to the wound. Warm water will be used for washing. Also, during the study in both groups, the wounds will be checked for infection and the day of the new infection will be recorded. Finally, the group will be matched in terms of blood sugar level and the type of blood sugar control drug will be recorded. The herbal medicine will be prepared in the laboratory of the Faculty of Traditional Medicine. The fruit is grafted and mixed with solvent (distilled water and alcohol in a ratio of 50:50) for 24 hours, then filtered and concentrated and stored in the refrigerator. The concentrated extract will be diluted 5 times with sterile distilled water.

Participants/Inclusion and exclusion criteria

Entry conditions: Type 2 diabetes patients, age 30 to 80 years, suffering from multiple or single debridement wounds Conditions of non-entry: acute diabetic foot ulcer, grade 3, 4, 5, addiction to drugs and alcohol, suffering from other chronic diseases other than diabetes, use of drugs effective in wound healing such as immunosuppressive, and allergic to the drug.

Intervention groups

In addition to routine treatment, the wound is washed with herbal extract and ordinary dressing: 3 times a day for 8 weeks.

Main outcome variables

Speeding up recovery - reducing hospitalization time - reducing treatment costs - patient satisfaction with treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230409057860N1**
Registration date: **2023-05-20, 1402/02/30**
Registration timing: **prospective**

Last update: **2023-05-20, 1402/02/30**
Update count: **0**

Registration date

2023-05-20, 1402/02/30

Registrant information

Name

ehsan sahbaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3771 9337

Email address

e24267s@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date
2023-09-21, 1402/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of the extract of the case compared to the conventional treatment (according to the protocol) in the treatment of diabetic foot ulcers after cutting in patients referred to Shahid Beheshti Hospital in Qom in 2023

Public title
Investigating the effectiveness of the extract of the case compared to the conventional treatment (according to the protocol) in the treatment of diabetic foot ulcers after cutting in patients referred to Shahid Beheshti Hospital in Qom in 2023
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with type 2 diabetes, men and women in the age range of 30 to 80 years, with multiple or single wounds that have been debrided. The wound of the patient in both groups is completely debrided before dressing so that no infection is observed. After debridement and washing the wound with water, the control group is given a normal dressing.
Exclusion criteria:
Acute diabetic foot ulcer, grade 3, 4, and 5 diabetic foot ulcer, drug and alcohol abuse; Suffering from a chronic disease other than diabetes that affects the wound healing process, such as severe vascular diseases, lupus, rheumatoid arthritis, Berger's and kidney failure, taking drugs that may interfere with wound healing, such as corticosteroids, immunosuppressive agents, and cytotoxic agents. , and sensitivity to herbal medicines used in the plan
Age
From **30 years** old to **80 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the random block sampling method will be used. The block randomization method is one of the randomization methods in order to balance the number of samples in each of the treatment groups while maintaining randomization. In this study, randomization method with fixed block size (size of each block is 4) has been used, for example AABB or BAAB block (A and B are the groups under study) that the way of allocating people and forming blocks using The output of the R software will be generated. This sampling method provides the possibility of performing intermediate analyzes with equal sample size in each group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qom University of Medical Sciences
Street address
Qom University of Medical Sciences
City
qom
Province
Ghoum
Postal code
3713649373
Approval date
2023-01-30, 1401/11/10
Ethics committee reference number
IR.MUQ.REC.1401.244

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Diabetic foot ulcer treatment
Timepoint
At the beginning of the study (before the start of the intervention) and 7, 14, 21, 28, 35, 42, 56 days after the start of the intervention
Method of measurement
A standard ruler is placed on the side of the wound and by taking a digital photograph of the leg wound, the area

of the wound will be calculated with the above standard scale in square centimeters by means of the exclusive area measurement software.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: It is a group that will be treated with a combination of medicinal plants in addition to treatment and routine care
Category
Treatment - Drugs

2

Description
Control group: It is a group that has undergone routine treatment after surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Salamat College, Faculty of Traditional Medicine, Medical Sciences, Qom
Full name of responsible person
Ehsan Sahbaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Dr. Rahim Alei
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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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Ehsan Sahbaei
Position
Surgical resident
Latest degree
Medical doctor
Other areas of specialty/work
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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
All the data will be published in the article and thesis after removing the names of the patients
When the data will become available and for how long
3 months after printing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
For scientific research
From where data/document is obtainable
Ehsan Sahbaei e24267s@gmail.com
What processes are involved for a request to access data/document
Submit an academic application and a description of your study and the need for data for this study
Comments