

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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 sahbai

##### 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

##### Street address

Qom University of Medical Sciences

##### City

Qom

##### Province

Ghoum

##### Postal code

3713649373

##### Phone

+98 25 3107 0100

##### Email

e24267s@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ghoum University of Medical Sciences

##### Full name of responsible person

Dr. Rahim Alei

##### Street address

Qom University of Medical Sciences

##### City

Qom

##### Province

Ghoum

##### Postal code

3713649373

##### Phone

+98 25 3107 0100

##### Email

e24267s@gmail.com

#### 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

General Surgery

##### Street address

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## Person responsible for scientific inquiries

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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****Person responsible for updating data****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**

General Surgery

**Street address**

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**City**

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**Postal code**