

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Investigating the effect of henna on the treatment of diabetic ulcers in patients with type 2 diabetes

#### Protocol summary

##### Study aim

Investigating the effect of henna in healing diabetic wounds in patients referred to clinics affiliated to Arak University of Medical Sciences

##### Design

A clinical trial with control and intervention groups, without blinding, on 66 patients.

##### Settings and conduct

The study is carried out in clinics affiliated to Arak University of Medical Sciences. The control group receives only normal saline, but the intervention group receives henna in addition to normal saline. First, 1 gram of henna powder leaves with 10 ml of distilled water is tested on the inner part of the forearm, if there is no sensitivity to henna extract, interventional treatment is started in the form that henna powder leaves are mixed with distilled water every 3 days, then for sterilization the composition, it is boiled for 10 minutes. After cooling, it is applied on the wound for 30 minutes and the results are evaluated after 15 days.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having type 2 diabetes At least 18 years old Exit criteria: Active wound infection The patient's unwillingness to participate in the study

##### Intervention groups

The control group receives only normal saline, but the intervention group receives henna in addition to normal saline. First, 1 gram of henna powder leaves with 10 ml of distilled water is tested on the inner part of the forearm, if there is no sensitivity to henna extract, interventional treatment is started in the form that henna powder leaves are mixed with distilled water every 3 days, then for sterilization the composition, it is boiled for 10 minutes. After cooling down, it is placed on the wound for 30 minutes.

##### Main outcome variables

Determining the severity of diabetic ulcer in the control and intervention groups before and after the intervention; Comparison of diabetic ulcer severity in the

control and intervention groups before and after the intervention

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160220026667N7**

Registration date: **2024-02-01, 1402/11/12**

Registration timing: **prospective**

Last update: **2024-02-01, 1402/11/12**

Update count: **0**

##### Registration date

2024-02-01, 1402/11/12

##### Registrant information

##### Name

Ali Jadidi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3508

##### Email address

jadidi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-08, 1403/01/20

##### Expected recruitment end date

2024-07-10, 1403/04/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of henna on the treatment of diabetic ulcers in patients with type 2 diabetes

**Public title**  
Investigating the effect of henna on diabetic wounds

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having type 2 diabetes At least 18 years old Living in Arak Willing to participate in the study No use of topical ointments  
**Exclusion criteria:**  
Active wound infection with clear purulent discharge or erythema of the wound margin or the presence of fever, radiographic clinical evidence of osteomyelitis Strong clinical evidence of serious insufficiency of lower limb circulation The patient's unwillingness to continue participating in the study

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **66**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**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 Arak University of Medical Sciences

##### Street address

Arak, Basij Square, Arak University of Medical Sciences

##### City

Arak  
**Province**  
Markazi  
**Postal code**  
3819693345

#### Approval date

2023-04-16, 1402/01/27

#### Ethics committee reference number

IR.ARAKMU.REC.1402.023

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes

#### ICD-10 code

E11

#### ICD-10 code description

Type 2 diabetes mellitus

## Primary outcomes

### 1

#### Description

Diabetic ulcers

#### Timepoint

Before the intervention and 15 days after the intervention

#### Method of measurement

Observation

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: use of normal saline and henna to wash the wound. First, one gram of henna powder leaf is tested with 10 ml of distilled water on the inner part of the forearm, and if there is no sensitivity to henna extract, interventional treatment is started. In this way, every three days, henna powder leaves are mixed with distilled water (ten milliliters of distilled water is added for each gram of henna powder leaves), then in order to sterilize the resulting mixture and destroy the microbes in it, It is boiled for 10 minutes. After cooling, the necessary amount (according to the size of the wound) is placed on the wound as a poultice for 30 minutes, and the results are evaluated after 15 days. Control group: use of normal saline to wash the wound

#### Category

Treatment - Drugs

## 2

### Description

Control group: Only normal saline is used to wash the wound.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam Reza Clinic

**Full name of responsible person**

Ali Jadidi

**Street address**

Khorram Street, Shiroudi Street

**City**

Arak

**Province**

Markazi

**Postal code**

3819693345

**Phone**

+98 86 3524 3417

**Email**

Jadidi.ali83@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Vice President of Research and Technology of Arak University of Medical Sciences

**Street address**

Sardasht, Basij Square, Prophet Azam University Complex, Faculty of Nursing

**City**

Arak

**Province**

Markazi

**Postal code**

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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**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Ali Jadidi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Sardasht, Basij Square, Prophet Azam University Complex, Faculty of Nursing

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**Phone**

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**Email**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Ali Jadidi

**Position**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

Regarding the data file and the individual data of the participants, it should be said that only part of the data, such as the information related to the healing or non-healing of the wound due to the use of henna, can be shared.

**When the data will become available and for how long**

The access period starts 3 months after the results are published

**To whom data/document is available**

The scientific information of this study will be available to all interested and researchers.

**Under which criteria data/document could be used**

People are allowed to use information for research and information gathering.

**From where data/document is obtainable**

People can request access to information by email at jadidi.ali83@yahoo.com.

**What processes are involved for a request to access data/document**

After the publication of the article, people can access the information by searching in reliable databases, otherwise, if they contact the mentioned email, people can announce their request and get their answer as soon as possible.

**Comments**