

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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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

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Email

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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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Person responsible for scientific inquiries

Contact

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

Arak University of Medical Sciences

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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