

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effects of Hydroalcoholic Extracts from *Achillea millefolium*, *Teucrium polium*, and Oak Fruit Inner Bark (*Quercus brantii*) Plants on the Healing of Skin Ulcers in Diabetic Patients - A Clinical Trial

Protocol summary

Study aim

The aim of this study is to determine the impact of hydroalcoholic extracts of *Achillea millefolium*, *Teucrium polium*, and oak fruit inner bark (*Quercus brantii*) plants on the healing of skin ulcers in diabetic patients.

Design

This is a randomized clinical trial with two parallel control and intervention groups, and a pilot study, involving a total of 25 patients. Randomization will be performed using the RAND function in Microsoft Excel.

Settings and conduct

The study will be conducted at the Diabetic Patients Clinic associated with YUMS. Eligible patients will be identified through physical examinations and review of their medical histories during the initial screening visit. Informed written consent will be obtained from each participant before any study-related procedures.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent to participate in the study. Exclusion criteria: Participation in another similar research. Receipt of radiation or chemotherapy in recent times. Use of local growth factors or biomedical products for ulcer treatment in the last 30 days. Sensitivity to the used plants. Smoking or drug use.

Intervention groups

Control Group: Diabetic patients with ulcers under standard treatment without receiving plant extracts.
Intervention Group: Diabetic patients with ulcers under standard treatment with the administration of plant extract.

Main outcome variables

Weekly clinical assessment of primary outcomes (complete ulcer healing) and secondary outcomes (reduction in ulcer size, tissue quality improvement, reduction in exudate, and history of side effects) will be evaluated using planimetry and photography at the initial visit and 3 weeks after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230523058265N1**

Registration date: **2023-11-18, 1402/08/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-18, 1402/08/27**

Update count: **0**

Registration date

2023-11-18, 1402/08/27

Registrant information

Name

Hassan Bardania

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3344 4079

Email address

hasan.bardania@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-02, 1402/07/10

Expected recruitment end date

2024-02-04, 1402/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Hydroalcoholic Extracts from Achillea millefolium, Teucrium polium, and Oak Fruit Inner Bark (Quercus brantii) Plants on the Healing of Skin Ulcers in Diabetic Patients - A Clinical Trial

Public title

The Effect of Hydroalcoholic Extracts of Yarrow, Felty Germander, and Oak Fruit Inner Bark on the Healing of Skin Ulcers in Diabetic Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent to participate in the study Wound area in the range of 0.5 to 36 cm² Duration of infection more than 4 weeks Age 18 or older

Exclusion criteria:

Participation in another similar research Receipt of radiation or chemotherapy in recent times Use of local growth factors or biomedical products for ulcer treatment in the last 30 days Sensitivity to the used plants Smoking or drug use

Age

From 18 years old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 25

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization codes will be generated using the RAND function in Microsoft Excel and will be used for the assignment of patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and statistical experts will remain blinded until the results are obtained and the statistical analyses are completed.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committees of Yasuj University of Medical Sciences

Street address

Dr. Shahid Jalil St.

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591994799

Approval date

2023-04-19, 1402/01/30

Ethics committee reference number

IR.YUMS.REC.1402.025

Health conditions studied

1

Description of health condition studied

Skin wound healing in diabetic patients

ICD-10 code

S01

ICD-10 code description

Open wound of head

Primary outcomes

1

Description

Percentage reduction in the area of diabetic ulcers

Timepoint

Up 3 weeks

Method of measurement

Ulcers will be measured in square centimeters using planimetry and photography.

Secondary outcomes

1

Description

Wound healing rate

Timepoint

Up 3 weeks

Method of measurement

Ulcers will be measured in square centimeters using planimetry and photography.

Intervention groups

1

Description

Intervention Group: Diabetic patients with diabetic ulcers receiving standard medications and herbal washing solution with daily consumption of a total concentration of 125 mg/ml of the extract of all three plants for three weeks.

Category

Treatment - Drugs

2**Description**

Control group: Diabetic patients with diabetic ulcers receiving standard medications

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Diabetic Clinic of Imam Sajjad Hospital, Yasuj

Full name of responsible person

Dr. Majid Ahmadi

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Dr. Shahid Jalil St.

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Web page address<https://emamsajad.yums.ac.ir/index.aspx?fkeyid=&siteid=52&pageid=8635>**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Yasuj University of Medical Sciences

Full name of responsible person

Dr Hassan Bardania

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Web page address<https://research.yums.ac.ir/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yasuj 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**

Yasuj University of Medical Sciences

Full name of responsible person

Dr Hassan Bardania

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Ph.D.

Other areas of specialty/work

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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

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information and results related to the effect of the extract on patients' wounds (anonymously)

When the data will become available and for how long

Beginning of the access period from 1403

To whom data/document is available

Patients and specialists

Under which criteria data/document could be used

They will be available for other researchers, but we need the permission from the ethics committee of the university.

From where data/document is obtainable

Hassan Bardania PhD of NanoBiotechnology Cellular and Molecular Research Center, Yasuj University of Medical Sciences Yasuj, Iran Email: hbardania@gmail.com Tel: 09190854796

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

About 1 month

Comments