Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 biomedicals 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 biomedicals 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
Kohgilouyeh-va-Boyrahmad

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 centers

1

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj 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
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Dr Hassan Bardania
Position
Assistant professor
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Medical Biotechnology
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Person responsible for updating data

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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