

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of potentially effectiveness of pomegranate husk extract topical gel on wound healing of diabetic foot ulcers: A randomized, parallel controlled phase II clinical trial

Protocol summary

Study aim

Evaluating the effectiveness of topical use of gel containing pomegranate husk extract in healing diabetic foot ulcers

Design

Clinical trial (phase 2) randomized controlled trial (RCT), two parallel groups, diabetic patients with diabetic ulcers in the lower limbs, number of 40 people, allocation ratio 1:1 using randomized block method (block size 4), unilateral blinding, patient follow-up for a maximum of 3 months

Settings and conduct

Place of study: Imam Reza Hospital of Kermanshah, one-way blinding (only the evaluator). In the control group, the usual wound care from the second day includes washing twice a day with water without betadine along with debridement. In the target group, in addition to the mentioned cases, a topical gel containing pomegranate husk extract (2.5%) is used topically.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetic patients with diabetic ulcers in the lower limbs without more than 50% reduction in the size of the ulcer during the last month. Exclusion criteria: Presence of bone and tendon, abscess with erythema and local sensitivity at the wound site, osteomyelitis, malignancy, use of anti-inflammatory drugs and growth factors in the last 2 weeks and radiotherapy in the last three months, lack of consent to participate in the study

Intervention groups

Control group: The usual wound care from the second day includes washing twice a day with water without betadine along with debridement if needed. Target group: In addition to the mentioned cases, topical gel containing pomegranate fruit peel extract (2.5%) is used and routine care is also performed

Main outcome variables

1) Duration of complete healing of the wound (initial) 2)

wound area before intervention and after intervention on days 7, 14, 21, and 30 (secondary)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221031056351N1**

Registration date: **2022-11-21, 1401/08/30**

Registration timing: **prospective**

Last update: **2022-11-21, 1401/08/30**

Update count: **0**

Registration date

2022-11-21, 1401/08/30

Registrant information

Name

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Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation of potentially effectiveness of pomegranate husk extract topical gel on wound healing of diabetic foot ulcers: A randomized, parallel controlled phase II clinical trial

Public title
Investigation of the effectiveness and usefulness of topical gel containing pomegranate husk extract in the healing of diabetic foot ulcers

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Diabetic patients with ulcers in the lower limbs who have not had more than a 50% reduction in the size of their ulcer during the last month.
Exclusion criteria:
 Evidence of bone and tendon, an abscess with local erythema and tenderness at the wound site, osteomyelitis, malignancy, use of anti-inflammatory drugs and growth factors in the last 2 weeks and radiotherapy in the last three months, and lack of consent to participate in the study.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by the random block method with a block size of 4. Unlike simple randomization, in which eligible patients are randomly assigned directly to treatments, in randomization with random blocks, patients are randomly assigned to the blocks in a sequence according to the size of the blocks, and finally, in each block of size 4, two patients will be randomly assigned to each intervention. Considering that the size of the blocks is assumed to be 4, there are six random arrangements or modes for the same allocation of patients to two interventions in each block, and this random sequence for the random allocation of patients to interventions in the block will be created by the methodology consultant. The rest of the project colleagues do not have access to the details of the random sequence until after the random allocation of patients.

Blinding (investigator's opinion)
Single blinded

Blinding description

The blinding will be unilateral, so that the evaluator who will follow the patient will be blinded to the type of intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Kermanshah University of Medical Sciences (Research Ethics Committee)
Street address
 No. 2 Central Building of Kermanshah University of Medical Sciences, Shahid Beheshti Street
City
 Kermanshah
Province
 Kermanshah
Postal code
 6714673159

Approval date
2022-06-21, 1401/03/31

Ethics committee reference number
IR.KUMS.REC.1401.225

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer caused by type 1 diabetes

ICD-10 code
10.5

ICD-10 code description
Type 1 diabetes mellitus with peripheral circulatory complications

2

Description of health condition studied
Diabetic foot ulcer caused by type 2 diabetes

ICD-10 code
11.5

ICD-10 code description
Type 2 diabetes mellitus with peripheral circulatory complications

Primary outcomes

1

Description

Duration of complete wound healing (initial)
Timepoint
at different times of 7, 14, 21 and 30 days
Method of measurement
Based on the diabetic foot ulcer assessment checklist

Secondary outcomes

1

Description
Wound area before intervention and after intervention on days 7, 14, 21, and 30 (secondary)
Timepoint
at different times of 7, 14, 21 and 30 days
Method of measurement
Based on the diabetic foot ulcer assessment checklist

Intervention groups

1

Description
Control group: The usual wound care from the second day includes washing twice a day with water without betadine along with debridement if needed.
Category
Treatment - Drugs

2

Description
Intervention group: In addition to the mentioned cases, a topical gel containing pomegranate fruit husk extract (2.5%) is used topically daily, and routine care is also performed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Masoud Fallahi
Street address
Imam Reza Hospital, next to the Medical School,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Zist Tolid Razi Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Hamidreza Mohammadmotlagh
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work

Medical Biology

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Person responsible for scientific inquiries

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Associate Professor

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

After patent registering of the study, it will be acted.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available