Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 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

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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, Nurse Boulevard, Sorkheh Lizheh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

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 Mohammadimotlagh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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Associate Professor

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General Surgery

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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