Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of a topical gel containing Sumac extract and Cloxacillin on diabetic foot ulcer: a double-blind placebo-controlled trial

Protocol summary

Study aim

Determining the effect of gel application on wound area and dimensions, wound healing time, healing pain caused by diabetic wound , patients' quality of life Determination of safety and tolerability of gel used in patients

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 on 66 patients

Settings and conduct

place of study : Diabetic foot ulcer clinic, University of Tehran Patients are included in the study based on inclusion and non-inclusion criteria and are assigned to the intervention or control group based on block randomization. Both types of gels have the same color, smell and appearance, and are poured into the same tubes. Each tube is assigned a code based on a table of random numbers and the researcher and the patient are not aware of it. The interventions will continue twice a day for 8 weeks. In case of infection in the wound during the study, infections will be treated.

Participants/Inclusion and exclusion criteria

inclusion criteria: Patients with type 1 or 2 Diabetes Age 30 years or older Grade 1 and 2 diabetic ulcers(Wagner classification system) Adherence to routine diabetes treatments ABI greater than 0.7 non-inclusion criteria: Pregnancy or Breastfeeding Presence of infection in the wound before admission Presence of neoplasia Use of immunosuppressive drugs

Intervention groups

Intervention group and control group Both groups receive routine treatment including debridement, infection control and treatment (if the wound becomes infected), hospitalization (if necessary), and off-loading procedures. The intervention group will be given Sumac-Cloxacillin gel and the control group will be given placebo gel.

Main outcome variables

Wound area a: Calculated weekly by wound imaging and computer software. Presence or absence of infection in the wound: It is checked weekly by visual observation when visiting the patient's wound.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220310054247N1**
Registration date: **2022-06-06, 1401/03/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-06, 1401/03/16**
Update count: **0**

Registration date

2022-06-06, 1401/03/16

Registrant information

Name

Fatemeh Azadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-05, 1401/03/15

Expected recruitment end date

2023-01-05, 1401/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of a topical gel containing Sumac extract and Cloxacillin on diabetic foot ulcer: a double-blind placebo-controlled trial

Public title

Effect of a topical gel containing Sumac extract and Cloxacillin on diabetic foot ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 1 or 2 Diabetes Age 30 years or older Grade 1 and 2 diabetic ulcers according to Wagner classification system Adherence to routine diabetes treatments Ankle Brachial Index (ABI) greater than 0.7

Exclusion criteria:

Pregnancy or Breastfeeding Presence of infection in the wound before admission Presence of neoplasia Use of immunosuppressive drugs

Age

From **30 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Multi-digit numerical codes (barcodes) are written on the packages that only the main person in charge of the research can open the codes if necessary and the type of medicine is specified. The codes are arranged in such a way that in the first ten codes, five packages contain one of the drugs and the other five packages contain the second drug. The same ratio is established in the second ten codes to the sixth ten codes. (Permuted Block Randomization) ABBAABABAB, BBAABABAAB, ABABBAABBA, AABABABABB, AAABABBBAB, BABABAABBA This type of design provides the conditions for intermediate tests, So that after the execution of each complete block, statistical tests can be performed, and if the result is reached and the difference between the two groups is significant, and the test power is maintained, the study can be stopped.

Blinding (investigator's opinion)

Double blinded

Blinding description

Sumac-cloxacillin gel and placebo gel both have the same color, smell and appearance and are poured into the same tubes. Each tube is assigned a code consisting of numbers and letters. These codes are distributed based on a table of random numbers between the drug and placebo groups and the researcher and the patient are not aware of it.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Deputy of research and technology, Saffarian Alley, Golshahr Ave.

City

karaj

Province

Alborz

Postal code

3198764653

Approval date

2022-03-06, 1400/12/15

Ethics committee reference number

IR.ABZUMS.REC.1400.330

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer caused by type 1 diabetes

ICD-10 code

E10.51

ICD-10 code description

Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene

2

Description of health condition studied

Diabetic foot ulcer caused by type 2 diabetes

ICD-10 code

E11.51

ICD-10 code description

Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene

Primary outcomes

1

Description

wound area and dimensions

Timepoint

Weekly for 8 weeks

Method of measurement

Photography of ulcers and Computer software

2

Description

Presence or absence of infection in the wound

Timepoint

Weekly for 8 weeks

Method of measurement

Wound examination and Visual observation

Secondary outcomes

1

Description

incidence of side effects

Timepoint

Evaluation will be weekly from the first week to the eighth week.

Method of measurement

Asking the patient and Examining the wound by the visitor (symptoms such as burning, itching, redness, etc. while using the gel)

2

Description

Tolerability

Timepoint

Evaluation will be weekly from the first week to the eighth week.

Method of measurement

Ask the patient if there is any discomfort while taking the drug or If there is any factor that makes the patient reluctant to continue treatment and the cause is related to the gel used.

3

Description

Pain assessment

Timepoint

Before the intervention and the end of the eighth week

Method of measurement

The patient scores from one to ten, depending on the amount of pain he feels.(Visual Analogue Scale)

4

Description

Quality of life score

Timepoint

Before the intervention and the end of the eighth week

Method of measurement

Questionnaire for quality of life of patients with diabetic foot ulcers.(Designed by Johnson in the UK, 1995)

Intervention groups

1

Description

Intervention group: Both groups (intervention and control) receive routine treatment including debridement, infection control and treatment (if the wound becomes infected), hospitalization (if necessary), and off-loading procedures. The intervention group receives a gel containing Sumac extract and Cloxacillin. The interventions are twice a day and will last for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Both groups (intervention and control) receive routine treatment including debridement, infection control and treatment (if the wound becomes infected), hospitalization (if necessary), and off-loading procedures. The control group receives placebo gel. Placebo gel contains gelling agent, water and preservative and does not contain Sumac extract and Cloxacillin. The interventions are twice a day and will last for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized Clinic for Diabetes and Metabolic Diseases affiliated to the Endocrinology and Metaboli

Full name of responsible person

kamelia Rambod

Street address

Specialized clinic for diabetes and metabolic diseases 1, Corner of Hayat Street, Shahrivar Street, North Kargar Ave.

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Sponsors / Funding sources

1

Sponsor

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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

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Ahmadian-Attari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Full name of responsible person

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In the case of patient data, only a portion of the data, such as information about the main outcome or the like, can be shared. The documents to be published will be published in the article. The general consent form is available at the University Vice Chancellor for Research.

When the data will become available and for how long

Start the access period: After publishing the article

To whom data/document is available

Researchers working in academic and scientific institutes, people working in industry

Under which criteria data/document could be used

Copying is prohibited. It is mandatory to follow the principles of referral.

From where data/document is obtainable

The applicant for the article can submit his request to the person in charge of updating the information or read the article in the published journal. Responsible for updating information: Fatemeh Azadi Contact number: 09124125372 Email: fazadi1998@gmail.com

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

The applicant can notify the applicant of the article by email or call, and the article will be emailed to the applicant within five days of the request.

Comments