

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of gel containing arginine-releasing chitosan nanofibers in the healing of diabetic foot ulcers: a randomized, controlled clinical trial

Protocol summary

Study aim

1. Determining the average wound size and number of erythema cases in experimental and control group patients at the before and end of weeks 1 and 2 of the intervention
2. Comparison of the number of cases of erythema at the end of weeks 1 and 2 of the intervention compared to before the intervention in patients in the experimental and control group
3. Comparison of mean percentage of wound reduction at the end of weeks 1 and 2 of the intervention and control group
4. Determining the number of cases of complete wound healing in the experimental and control group

Design

Random clinical trial with control group

Settings and conduct

1. The study is performed in different wards of Al-Zahra Hospital.
2. Demographic and clinical information of the subjects.
3. Grouping and intervention is done.
4. Using statistical analysis.

Participants/Inclusion and exclusion criteria

1. Grade 1 or 2 diabetic foot ulcers in one or more areas
2. Do not smoke now
3. Do not take anticoagulants and immunosuppressive and supplements effective in wound healing (phenytoin, glucocorticoids, anti-cancer drugs and products containing vitamin C, vitamin A or Zinc) in the last 3 months
4. Do not have chronic vascular insufficiency with a cause other than diabetes and No coagulation disorders (such as hemophilia)

Intervention groups

patients will be randomly divided into experimental and control groups (block randomization method using quadruple blocks). For the experimental group, chitosan gel once a day with dressing and other routine care including debridement, Rinse with normal saline and prescribe antibiotics if necessary and control blood sugar and for people in the control group, a new dressing once a day and routine care. It will be prescribed for 2 weeks.

Main outcome variables

Percentage reduction in wound size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023282N16**

Registration date: **2021-03-25, 1400/01/05**

Registration timing: **prospective**

Last update: **2021-03-25, 1400/01/05**

Update count: **0**

Registration date

2021-03-25, 1400/01/05

Registrant information

Name

Rasool Soltani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7067

Email address

soltani@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of gel containing arginine-releasing chitosan nanofibers in the healing of diabetic foot ulcers: a randomized, controlled clinical trial

Public title

Effect of arginine in diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Grade 1 or 2 diabetic foot ulcers in one or more areas

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 22

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method using blocks of size 4 will be used. So that all possible sequences of two drug and two placebo in each block will be made with each block being numbered. Then, using random number table, the blocks will be selected randomly and the patients will be assigned to the two groups of drug and placebo according to the the blocks sequences.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Vice-chancellery for research, Isfahan University of Medical Sciences, Hezar-Jerib Avenue, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-07-09, 1399/04/19

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.419

Health conditions studied**1****Description of health condition studied**

diabetic foot ulcer

ICD-10 code

E11.621

ICD-10 code description

Type 2 diabetes mellitus with foot ulcer

Primary outcomes**1****Description**

Ulcer reduction percentage

Timepoint

The beginning of the intervention 7 and 14 days after the intervention

Method of measurement

Ruler

Secondary outcomes**1****Description**

The number of cases of erythema around the ulcer

Timepoint

The beginning of the intervention 7 and 14 days after the study

Method of measurement

Observation

Intervention groups**1****Description**

Intervention group: Chitosan gel (the amount needed to create a layer 3 mm thick on sterile gauze and placed on the wound surface, so as to cover the entire wound surface), once a day with dressing and other routine care including Debridement, rinsing with normal saline and antibiotics will be prescribed for 2 weeks if necessary and blood sugar control. The wound will be washed before applying the gel.

Category

Treatment - Drugs

2

Description

Control group: The control group will be given a new dressing (the type of which will be determined based on the type of wound and only one of them will be included in the study) once a day and routine care for 2 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Rasool Soltani

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Hagh Joo Javanmard

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Position

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Latest degree

Specialist

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

It is not necessary

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