

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Evaluation of the effect of Cow milk topical ointment on diabetic foot ulcer and bedsore healing

Protocol summary

Study aim

Determining the effectiveness of topical milk ointment in the healing of diabetic foot ulcer and bedsore

Design

Two arm parallel group randomised trial with control group

Settings and conduct

The study will be performed in Al-Zahra hospital of Isfahan. Patients with the inclusion criteria will be randomly assigned to drug or control groups. The sample size is 60 patients. For patients in drug group, milk 20% topical ointment will be applied for two weeks, while for patients of control group, specific dressing (Aquacel-Ag) will be used for two weeks. At the end of 7th and 14th day of intervention, the percent of wound size reduction and the erythema status will be recorded. Furthermore, the number of cases with complete wound healing during the study will be recorded for both groups. Finally, the mentioned variables will be compared between the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age of 18 years-old or more 2. Diabetic foot ulcer grade 1 or 2 or bedsore stage 2 or 3
Exclusion criteria: 1. Smoking 2. Coagulopathy

Intervention groups

Drug Group: Topical ointment 20% cow's milk (made by faculty of pharmacy of Isfahan university of medical sciences), once daily concurrent with routine wound care including irrigation with normal saline solution, dressing, and antibiotic administration, if necessary, for two weeks
Control Group: Specific dressing (Aquacel-Ag, made by Convatec company, USA), once daily concurrent with routine wound care including irrigation with normal saline solution, dressing, and antibiotic administration, if necessary, for two weeks

Main outcome variables

1. The percent of decrease in the wound size 2. The number of cases of complete wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023282N8**

Registration date: **2020-01-30, 1398/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-30, 1398/11/10**

Update count: **0**

Registration date

2020-01-30, 1398/11/10

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

2020-01-21, 1398/11/01

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Cow milk topical ointment on diabetic foot ulcer and bed sore healing

Public title

Effect of Cow milk topical ointment on wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic foot ulcer grade 1 or 2 Bed sore stage 2 or 3

Exclusion criteria:

Smoking Use of Anticoagulant Drugs Within the Last 3 Months

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method will be used. For this, patients with even and odd medical profile numbers, respectively, will be assigned to drug and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

Isfahan University of Medical Sciences, Hezar-Jerib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-01-06, 1398/10/16

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.595

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

Percent of Decrease in Ulcer Size

Timepoint

Baseline, 7 and 14 Days after Initiation of Intervention

Method of measurement

Ruler

2

Description

The Number of Cases of Complete Ulcer Healing

Timepoint

During the Intervention

Method of measurement

Observation

Secondary outcomes

1

Description

The Number of Cases with Peri-Ulcer Erythema

Timepoint

Baseline, 7 and 14 Days after Initiation of Intervention

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Milk topical ointment, Isfahan University of Medical Sciences, Isfahan University of Medical Sciences, once daily with daily wound healing and dressing for 14 days

Category

Treatment - Drugs

2

Description

Control group: Control group: Special dressing (made in

Convatec company, USA), once daily, with wound irrigation, for 14 days

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Rasool Soltani

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Soffeh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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7346181746

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research@mui.ac.ir

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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Person responsible for scientific inquiries

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Full name of responsible person

Rasool Soltani

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

There is no necessity.

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