Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of ointment based on ostrich oil containing honey, beeswax and ethanolic extracts of propolis, senna angustifolia and nigella sativa on wound healing on diabetic foot ulcer

Protocol summary

Study aim

The effect of ointment based on ostrich oil containing honey, beeswax and ethanolic extracts of propolis, senna Angustifolia and Nigella sativa on wound healing on diabetic foot ulcer

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 and 3 per 120 patients. Excel software rand function was used for randomization.

Settings and conduct

Random sampling is convinient in patients referred to the Sedigheh Tahereh Hospital of Isfahan University of Medical Sciences who have diabetic ulcers.The study is double-blind. The number of participants is 120. The doctor and the participants do not know how to be in the groups. Every day, one gram of prepared ointment and one gram of Eucerine (placebo) is rubbed on the wounds of patients in the placebo and treatment group. It is worth noting that none of the common treatments are discontinued. The wound condition is checked every week by a specialist doctor. The wound area is measured with a caliper.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Grade 0, 1 and 2 foot ulcers Controlled blood sugar Exclusion criteria: 1. Consumption of cigarettes and alcoholic beverages 2. Taking anticoagulants 3. Taking immunosuppressive drugs 4. Having hemophilia 5. Use of drugs effective in wound healing (phenytoin, glucocorticoids, anti-cancer drugs and NASIDs) 6. Acute lower extremity circulatory failure

Intervention groups

In the treatment group, we use from new formulation (an ointment based on ostrich oil containing beeswax, honey, propolis) for treatment of diabetic ulcers. In control group, we use from Eucerin as placebo. the Eucerin has not any effect on wound healing process.

Main outcome variables

The main outcome is the area of the wound and the depth of the wound, which is measured by a caliper.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200728048230N1**
Registration date: **2020-08-15, 1399/05/25**
Registration timing: **prospective**

Last update: **2020-08-15, 1399/05/25**
Update count: **0**

Registration date

2020-08-15, 1399/05/25

Registrant information

Name

Anousheh Zargar Kharazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5265

Email address

a_zargar@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of ointment based on ostrich oil containing honey, beeswax and ethanolic extracts of propolis, senna angustifolia and nigella sativa on wound healing on diabetic foot ulcer

Public title
effect of ointment on diabetic ulcer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
First and second degree wounds in Diabetic patient Regulated blood sugar
Exclusion criteria:
Weak immune system Bone infection Angiogenic disorder
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples were randomly divided into two experimental groups a or b. To do this, cards of the same shape and size on which a or b is written are placed in a box and each sample is asked to randomly select a card. People who take card a are in the test group and people who take card b are in the placebo group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient and the clinician do not know the type of ointment. Ointments are similar in color and smell.
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
Hezar jerib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-07-27, 1399/05/06
Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.201

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer
ICD-10 code
L97
ICD-10 code description
Ulcer of lower limb, not elsewhere classified

Primary outcomes

1

Description
surface of wound
Timepoint
From the beginning of the study, the wound is photographed every seven days for two months.
Method of measurement
The wound area is measured using a ruler or caliper.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the experimental group receive routine treatment of diabetic foot ulcer (including topical or topical or systemic antibiotics) along with topical ointment with a new formulation once a day for 2 months.
Category
Treatment - Drugs

2

Description

Control group: Patients in the control group receive standard treatment for diabetic foot ulcer with placebo (Eucerin base) once a day for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine and Metabolism Research Center (Sedigheh Tahereh), Isfahan

Full name of responsible person

Anousheh zargar kharazi

Street address

khoram street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3335 9933

Email

emrc@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Anousheh Zargar Kharazi

Street address

hezar jerib

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 5265

Email

a_zargar@med.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

darioush khodabakhshi

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Tissue Engineering

Street address

hezar jerib

City

Isfahan

Province

Isfehan

Postal code

8841657183

Phone

+98 38 3257 4575

Email

darioush1373@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

darioush khodabakhshi

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Medical Engineering

Street address

hezar jerib

City

Isfahan

Province

Isfehan

Postal code

8841657183

Phone

+98 38 3257 4575

Email

darioush1373@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Anousheh Zargar Kharazi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Tissue Engineering

Street address
HezarJerib Street

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3198 5265

Email
a_zargar@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Not all data will be available.

When the data will become available and for how long
The clinical article will be awaited after the completion of the trial.

To whom data/document is available
Researchers and research companies can access the data.

Under which criteria data/document could be used
Data will be available in the case of a scientific or commercial contract.

From where data/document is obtainable
Please connect via below email: a_zargar@med.mui.ac.ir

What processes are involved for a request to access data/document
Upon request, the researcher submits the data up to one month after the request.

Comments