Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of topical cream of Chelidonium majus and Hyoscyamus niger with Propolis on diabetic foot ulcers

Protocol summary

Study aim
the effect of topical cream containing Chelidonium majus and and Hyoscyamus niger with propolis on healing of diabetic foot ulcer

Design
The clinical trial is designed as an intervention with a control group, double-blind, randomized, in phase 3 on 88 patients.

Settings and conduct
A double-blind study is performed on 88 patients with diabetic ulcers in Shahid Beheshti of Kashan and Al Zahra of Isfahan hospitals. The doctor and the patient do not know the type of treatment. The patients receive topical cream containing Chelidonium majus and Hyoscyamus niger with Propolis during three weeks. The duration of each cream will be 6 days and the treatment will be done once a day.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diabetic patients who take insulin, have diabetic foot ulcers and are in the age range of 18 to 85 years. Clinical judgment of the specialist physician based on receiving the product of patient's ability and its personal desire to fill out of personal consent form to enter the study. Exclusion criteria: Existence of any history of allergy to any herbal product. Patients who need to surgery for their wounds

Intervention groups
Intervention group: Includes 44 patients with diabetic foot ulcers. These patients receive topical cream containing Chelidonium majus and Hyoscyamus niger with Propolis during three weeks. The usage duration of each cream will be 6 days and the treatment will be done once a day. Control group: Placebo will be used in addition to standard treatment in patients with diabetic foot ulcers for three weeks.

Main outcome variables
1- The extent of the wound 2- Angiogenesis 3- Tissue improvement 4- Duration of treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200516047462N3**
Registration date: **2021-11-23, 1400/09/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-23, 1400/09/02**
Update count: **0**

Registration date
2021-11-23, 1400/09/02

Registrant information

Name
morteza kosari
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
2021-11-21, 1400/08/30

Expected recruitment end date
2022-06-20, 1401/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of topical cream of Chelidonium majus and Hyoscyamus niger with Propolis on diabetic foot ulcers

Public title
The effect of Chelidonium majus and Hyoscyamus niger with Propolis on diabetic foot ulcers

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with diabetes who take insulin and have diabetic foot ulcers and are in the age range of 18 to 85 years. Clinical judgment of the specialist physician based on receiving the product The patient's ability and its personal desire to fill out of personal consent form to enter the study

Exclusion criteria:
Existence of any history of allergy to any herbal product Patients who need surgery for their wounds

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are divided into two groups by terminated block randomization method with blocks of 4 and 6, prescription drugs (intervention and placebo) are determined based on this method and a special number is assigned to them Physician and patient are unaware of drug or placebo receiving and there are codes that were registered on cream and only the epidemiologist informs as a plan executor.

Blinding (investigator's opinion)
Double blinded

Blinding description
A cream that has an active ingredient with a cream that does not have a substance and is used as a placebo is completely identical in terms of the shape and size of the container, and the solution themselves do not differ in terms of color, and are completely indistinguishable. The important point is that the patient is told that the topical cream used for the patient may be medication or medication. Clinicians and patients will be blinded

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
Ghotb Ravandi Blvd, Shahid Beheshti Hospital, University of Medical Sciences, Kashan, Iran.

City
Kashan

Province
Isfehan

Postal code
87159/81151

Approval date
2021-06-26, 1400/04/05

Ethics committee reference number
IR.KAUMS.REC.1400.014

Health conditions studied

1

Description of health condition studied
Diabetic food ulcers

ICD-10 code
L97

ICD-10 code description
Ulcer of lower limb, not elsewhere classified

Primary outcomes

1

Description
Size and extent of wound

Timepoint
At the beginning of the study, 4 days after treatment and 7 days after treatment, 14 days after treatment, 21 days after treatment

Method of measurement
In millimeters

2

Description
The infiltration of inflammatory cells, neutrophils, monocytes, synthesis and maturation of collagen, fibroblasts and keratinocytes and induction of angiogenesis

Timepoint
21 days after treatment

Method of measurement
Tissue sample

3

Description
Nuclear hypertrophy of endothelial cells, vacuoles,

diabetic foot ulcer granulation and tissue fibrosis

Timepoint

Twenty one days after treatment

Method of measurement

Histology

4

Description

The duration of treatment, the speed of recovery, the rate of symptoms reduction and the duration of disease recurrence

Timepoint

Twenty one days after treatment

Method of measurement

Check list

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group is included 44 patients with diabetic foot ulcers. During three weeks, topical cream containing 0.5 grams of Chelidonium majus and 0.5 grams of Hyoscyamus niger with 2 grams of Propolis is used. The duration of each cream will be 6 days and the treatment will be done once a day. The patient receives a maximum of 3 creams during the treatment period.

Category

Treatment - Drugs

2

Description

The control group includes 44 patients with diabetic foot ulcers with Wegener 1, 2 and 3 and according to standard treatment receive medication along with placebo. Topical cream with no active ingredients is used for three weeks. The duration of use of each cream will be 6 days. The patient receives a maximum of 3 creams during the treatment period.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Kashan

Full name of responsible person

Morteza kosari

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Ghotb Ravandi Blvd, Shahid Beheshti Hospital of Kashan

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2

Recruitment center

Name of recruitment center

Al-Zahra Hospital of Isfahan

Full name of responsible person

Morteza kosari

Street address

Al-Zahra Hospital, Sofeh Blvd, Shahid Keshvari Highway, Isfahan Blvd, Shahid Keshvari Highway, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Banafsheh

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research@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Kashan University of Medical Sciences

Proportion provided by this source
10

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Morteza Kosari

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Physiology

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

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

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
Information about participants such as age, gender, level of education and employment will be reported. The treatment protocol and the duration of treatment process will be reported. Therapeutic results of the product and possible side effects will be reported.

When the data will become available and for how

long

The start of the access period will be 6 months after patent presentation or 12 months after article publication.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutes.

Under which criteria data/document could be used

The data printed in the article is accessible.

From where data/document is obtainable

Moderator: Morteza Kosari Email address: kosarimorteza12@gmail.com

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

This access will be based on the treatment protocol in hospitalized patients and treatment results, and includes effective ingredients and how to make the privacy cream of the project implementers. We will try to respond to researchers as soon as possible.

Comments