Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of efficacy and safety of topical application of ring worm extract (eisenia foetida) in the treatment of diabetic foot

Protocol summary

Study aim
Determination of the efficacy and safety of topical application of ring worm extract (eisenia foetida) in the treatment of diabetic foot ulcer

Design
Patients are divided into two intervention and control groups by simple randomization method. According to the trial phase of 2-3, the sample size will be in two groups of 20 people. In this study, no blinding will occur.

Settings and conduct
This study will be performed on 20 diabetic patients with Grade 1 and 2 foot ulcer and no blinding will occur in this study. Patients receive usual wound care and treatment and dressing. In addition, the intervention group receives eisenia fida extract under dressing.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Type 2 Diabetes Mellitus for at least 5 years, age between 30 to 65 years, Body Mass Index (BMI) between 18 and 35, Wagner grade of 1 and 2. Exclusion criteria: Lack of patient's follow-up, Patient dissatisfaction at each stage of the study, Complications caused by treatments during study, Creation of acute or severe complications of diabetes due to exacerbation of underlying illness, Having other systemic diseases that may affect the ulcer Use of tobacco, alcohol, narcotics, cytotoxic drugs and glucocorticoid and immunosuppressive drugs, Pregnancy and breast feeding, Wagner grade of 3 to 5, HbA1C hemoglobin level of more than 10

Intervention groups
Intervention group: Patients, in addition to usual care and treatment, after daily wound washing with normal saline receive topical eisenia fida extract (G-90 extract) under dressings. Control group: Patients receive regular and standard treatment and daily wound washing with normal saline and also use Vaseline under dressing.

Main outcome variables
Percentage of wound healing, percentage of reduction in wound area (size)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180523039810N1**
Registration date: **2018-07-08, 1397/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-08, 1397/04/17**
Update count: **0**

Registration date
2018-07-08, 1397/04/17

Registrant information

Name
Bita Kiafar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3858 3845

Email address
kiafarb@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-10, 1396/10/20

Expected recruitment end date
2020-01-10, 1398/10/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of efficacy and safety of topical application of ring worm extract (eisenia foetida) in the treatment of diabetic foot

Public title
Evaluation of efficacy of topical application of ring worm extract in the treatment of diabetic foot
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Type 2 Diabetes Mellitus for at least 5 years Age between 30 to 65 years Body Mass Index (BMI) between 18 and 35 Wagner grade of 1 and 2
Exclusion criteria:
Lack of patient's follow-up Patient dissatisfaction at each stage of the study Complications caused by treatments during study Creation of acute or severe complications of diabetes due to exacerbation of underlying illness Having other systemic diseases that may affect the ulcer Use of tobacco, alcohol, narcotics, cytotoxic drugs and glucocorticoid and immunosuppressive drugs. Pregnancy and breast feeding Wagner grade of 3 to 5 HbA1C hemoglobin level of more than 10
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to two groups of intervention and control using simple randomization method.
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 Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
345 - 91357
Approval date
2018-01-10, 1396/10/20
Ethics committee reference number
IR.MUMS.fm.REC.1396.551

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Rate of patient's wound size improvement
Timepoint
At the beginning of the treatment and monthly follow up until 3 months after first ointment use
Method of measurement
The percentage of recovery is calculated as a percentage of wound size reduction (measured on a millimeter basis) including length-width-depth (by sterile swab) per visit.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: 600-mg Clindamycin for every 8 hours and 500-mg ciprofloxacin for every 12 hours are prescribed. Wound washing with normal sterile saline, use of Vaseline on the wound and dressing change twice a day, and control of fasting blood sugar are carried out daily.
Category
Treatment - Drugs

2

Description
Intervention group: 600-mg Clindamycin for every 8 hours and 500-mg ciprofloxacin fore every 12 hours are prescribed. After daily wound washing with normal sterile

saline, the topical eisenia foetida extract is used under the dressing. The dressing is changed twice a day, and Fasting blood sugar control is carried out daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Zahra Mazlum Khorasani

Street address

Ghaem hospital, Ahmad Abad Ave

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9176699199

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mazloumz@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Bita Kiafar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Email

kiafarb@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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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

Yes - There is 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

All data can be shared after patients are made unidentifiable

When the data will become available and for how long

Data can be accessible 6 months after results are published

To whom data/document is available

All academic institutes and non-academic industrial institutes which are related to our studies will have access to our data after going through legal procedures.

Under which criteria data/document could be used

In case those people asking for data have the intention of optimizing the study an data and producing more results, access to data is allowed.

From where data/document is obtainable

Through sending an email to the corresponding author, data will be obtainable.

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

In case someone asks for data, he must first get in contact with the corresponding author for his identity to be fully verified. Then if university allows propagation of data, it will be accessible in 3 months

Comments