Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Lucillia Sericata larval therapy in the treatment of diabetic chronic wounds

Protocol summary

Study aim
Lucillia Sericata larval therapy in the treatment of diabetic chronic wounds

Design
70 patients with chronic diabetic ulcers use sterile larvae. Randomization is not real. Only on the basis of the physician's diagnosis and inclusion criteria, the informed consent form is obtained from the candidates and blinding can not be done. The study has no control group.

Settings and conduct
Washing the wound with saline serum, the area around the wound is covered with zinc oxide. Depending on the degree of infection and the size of the wound, a suitable number of larvae are placed on the wound surface and after performing the dressing and fixing it, the patient will be discharged and will return to change the dressing 48 hours later. The results before and after treatment are compared with each other. Patients are examined directly under the supervision of an internal medicine specialist and the results are sent to surgeon colleagues. The place of study is Mahdieh Hamedan specialized clinic.

Participants/Inclusion and exclusion criteria
inclusion criteria: Diabetic patients (more than 15 years old) with chronic wound that signed the informed consent. Exclusion criteria: Patients who taking wound healing drugs. immunosuppress patients. scares> 5cm. patients with osteomyelitis, cellulitis and cancers. patients who needs amputation or flap surgery. Patients with vascular problems that needs surgery. Wet wounds. new wounds. More than one wound. smoker burger disease. ecxema or skin allergy history. Chemotherapy or radiotherapy history. Any sensitivity to special drug.

Intervention groups
In chronic diabetic wounds: The area around the wound is covered with zinc oxide ointment. An appropriate number of sterile larvae are placed on the wound surface and the wound is covered with sterile gauze and a cotton band.

Main outcome variables
Investigation and evaluation of wound size by wound sizing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201012049000N1**
Registration date: **2020-12-21, 1399/10/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-21, 1399/10/01**
Update count: **0**

Registration date
2020-12-21, 1399/10/01

Registrant information

Name
Hajar Khazraei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3628 1453

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khazraee@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2021-05-21, 1400/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Lucillia Sericata larval therapy in the treatment of diabetic chronic wounds

Public title
Lucillia Sericata larval therapy in the treatment of diabetic chronic wounds
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic patients (more than 15 years old) with chronic wound that signed the informed consent.
Exclusion criteria:
Consumption of drugs that influence the wound healing. immunosuppress patients like hemophilia and hepatic disease. scares> 5cm patients with osteomyelitis, cellulitis and cancers. patients who needs amputation or flap surgery. Patients with vascular problems that needs surgery. Wet and new wounds. More than one wound. smoker or burger disease Claudication or vascular graft problems. HbA1C>8 ESR, CRP>+1 anticouagulation therapy. wound under pressure. fear of insects. ecxema or skin allergy history. Chemotherapy or radiotherapy history. Any sensitivity to special drug.
Age
From **15 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Colorectal research center, Research tower, Khalili Street
City
Shiraz
Province
Fars
Postal code
7193635899
Approval date
2020-07-27, 1399/05/06
Ethics committee reference number
IR.SUMS.REC.1399.826

Health conditions studied

1

Description of health condition studied
Diabetic wound
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Investigation and evaluation of wound size by wound sizing
Timepoint
before intervention and 7 days after
Method of measurement
Evaluation and evaluation of wound size by wound sizing with standard measuring device (strotactic)

Secondary outcomes

1

Description
Inflammation and redness or infection at the site of the wound
Timepoint
before intervention and 7 days after
Method of measurement
Medical visit

Intervention groups

1

Description
Intervention group: 70 patients with diabetic wounds were treated by maggot therapy. First, after washing the wound with saline serum, the area around the wound is covered with zinc oxide ointment. Depending on the

degree of infection and the size of the wound, a suitable number of larvae are placed on the wound surface and after performing the dressing and fixing it, the patient will be discharged and will return to change the dressing 48 hours later. The wound size by wound sizing before and after treatment are compared with each other. Patients are examined directly under the supervision of internal medicine specialist and the results are sent to surgeon colleague.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra hamedan Clinic

Full name of responsible person
Arash Jafari

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Mahdyeh Clinic, Mahdyeh street, Hamedan

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Abbas Rezaeianzadeh

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Shiraz University of Medical Sciences, Zand street, Shiraz

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rezaiana@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Hajar Khazraei

Position
Assisstant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Arash Jafari

Position
Assisstant professor

Latest degree
Ph.D.

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Parasitology

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Person responsible for updating data

Contact

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Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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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
Because of Secret data of patients

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

Statistical Analysis Plan
Not applicable

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
No - There is not 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
Size of wounds Inflammation, redness infection

When the data will become available and for how long
one year

To whom data/document is available
Professors

Under which criteria data/document could be used
Future Research

From where data/document is obtainable
First Author

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

Comments