

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 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 Mahdiah 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)

Phone

+98 71 3628 1453

Email address

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. scars > 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. eczema 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

Street address

Mahdyeh Clinic, Mahdyeh street, Hamedan

City

Malayer

Province

Hamadan

Postal code

7193635899

Phone

+98 81 3838 0044

Email

arash.jafari87@gmail.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaeianzadeh

Street address

Shiraz University of Medical Sciences, Zand street,
Shiraz

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ ۷۱۳۴۸

Phone

+98 71 3230 5410

Email

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

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Colorectal Reserach Center, Research tower, Khalili
Street

City

Shiraz

Province

Fars

Postal code

7193635899

Phone

009836281453

Email

hajarkhazraei@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Arash Jafari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Parasitology

Street address

Daneshjoo BLV. Malayer

City

Malayer

Province

Hamadan

Postal code

۶۵۷۱۹۶۱۶۶۸

Phone

0098813227878

Email

arash.jafari87@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hajar Khazraei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Colorectal Research Center, Research tower, Khalili Street

City

Shiraz

Province

Fars

Postal code

7193635899

Phone

+98 71 3628 1453

Email

hajarkhazraei@gmail.com

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