

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effectiveness of maggot therapy in removing necrotic tissues and pathogenic bacteria in diabetic foot ulcers in grade of Wagner 2

Protocol summary

Study aim

To evaluate the efficacy of Maggot Therapy with *Lucilia sericata* in treatment of diabetic foot ulcers as a clinical trial

Design

Block randomization method will be used for random allocation. The blocks size will be 4 and for this purpose, 25 blocks with 4 subjects in each block will be used. the combination of all patterns will be considered including AABB, ABAB, BABA, BBAA, BABA, BAAB. For selecting each blocks, dice dropped and the bloc number will be selected. this procedure continued to completed the allocation and reached to sample size.

Settings and conduct

This study was conducted as a clinical trial study with 56 patients who referred to diabetes clinic of Shahid Beheshti Hospital affiliated to Qom University of Medical Sciences. Patients must sign an informed consent form before entering the study. Blinding will not be done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with at least one diabetic foot ulcer, no need for anticoagulant or steroid pharmaceuticals; not addicted to alcohol or opium.
Exclusion criteria: Acquiring sever diseases such as heart disorders and so on, sever pain during maggot therapy, sever and uncontrolled fever during maggot therapy

Intervention groups

Patients entered into the study are divided into two groups of control and intervention. Both groups will take routine treatments for diabetic foot ulcers. Routine therapy involves local and systemic measures, including blood glucose uptake, debridement, wet dressing, nutritional support, and antibiotic therapy. Patients in the intervention group, in addition to routine therapies, will receive maggot therapy as a method along with routine methods. Patients in the control group will be treated

with routine methods only.

Main outcome variables

Removing of necrotic tissues; appearing of granulated tissues; removing of main bacteria from the wounds

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170723035248N2**

Registration date: **2018-03-21, 1397/01/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-21, 1397/01/01**

Update count: **0**

Registration date

2018-03-21, 1397/01/01

Registrant information

Name

Abedin Saghafipour

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25 3784 2228

Email address

asaghafi@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Qom University of Medical Sciences

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of maggot therapy in removing necrotic tissues and pathogenic bacteria in diabetic foot ulcers in grade of Wagner 2

Public title

Efficacy of maggot therapy on diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who have at least one diabetic foot ulcer (grade s, Wagners' classification). Patients who have not osteomeyelies. Patients who have not need to be hospitalized. Patients who have not acute or other chronic diseases. Patients who have not need anticoagulant or steroid pharmaceuticals. Patients who have not addicted to alcohol or opium.

Exclusion criteria:

Patients who have sever diseases such as heart disorders and so on during maggot Therapy. Patients who have sever pain during maggot Therapy. Patients who get sever and un-controlled fever during maggot therapy. Patients with maceration around the wound after each interval of maggot therapy. Patients who need emergent hospitalization during or after of each interval of maggot therapy. Patients who take bleeding during maggot therapy.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **56**

Actual sample size reached: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, block randomization method will be used for random allocation. The blocks size will be 4 and for this purpose, 25 blocks with 4 subjects in each block will be used. the combination of all patterns will be considered including AABB, ABAB, BABA, BBAA, BABA, BAAB. For selecting each blocks, Dice drooped and the bloc number will be selected. this procedure continued to completed the allocation and reached to sample size.

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 Qom University of Medical Sciences

Street address

Ghoush University of Medical Sciences, Safa Shahr Avenue, Building of Research and Technology Deputy

City

Ghoush

Province

Ghoush

Postal code

37169-87366

Approval date

2017-07-04, 1396/04/13

Ethics committee reference number

IR.MUQ.REC.1396.41

Health conditions studied**1****Description of health condition studied**

Diabetic foot ulcer

ICD-10 code

L98.4

ICD-10 code description

Chronic ulcer of skin NOS

Primary outcomes**1****Description**

measuring surface of necrotic tissue

Timepoint

48 and 96 hours after treatment

Method of measurement

photographing and measuring by MATLAB 1.6, the mathworks Inc, natic, ma, 2000

Secondary outcomes**1****Description**

Bacterial infections, Staphylococcus aureus and

Pseudomonas aeruginosa

Timepoint

48 and 96 hours after treatment

Method of measurement

culturing of samples in laboratory

Intervention groups

1

Description

Intervention group: In addition to receiving the routine treatment that the control group will receive, the prescription of the larvae of the flies (*Lucilia sericata* larvae) is also used to treat diabetic foot ulcer. Routine therapy involves local and systemic measures, including blood glucose uptake, debridement, wet dressing, nutritional support, and antibiotic therapy. The number of larvae per wound in order to maggot therapy as process in healing of wounds, varies. It is depending on the extent and depth of the wound and the degree of infection in different parts of the damaged site in the wound. But usually, there are 8 to 10 larvae per cm² of ulcer. Interventions will be done every 48-72 hours. Interventions in this plan will only be carried out by a licensed medical staff such as a doctor and a nurse. In this plan, the duration of the intervention will be until complete remove of the necrotic tissue.

Category

Treatment - Surgery

2

Description

Control group: They will receive only routine treatment for diabetic foot ulcers.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mahmood Parham

Street address

Ghoum University of Medical Sciences, Safa Shahr Avenue, Building of Research and Technology Deputy

City

Ghoum

Province

Ghoum

Postal code

37169-87366

Phone

+98 25 3285 4011

Fax

+98 25 3783 3361

Email

dr.hosseinsaghafi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Hossein Saghafi

Street address

Ghoum University of Medical Sciences, Safa Shahr Avenue, Building of Research and Technology Deputy

City

Ghoum

Province

Ghoum

Postal code

37169-87366

Phone

+98 25 3285 4011

Fax

+98 25 3783 3361

Email

dr.hosseinsaghafi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

Abedin Saghafipour

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Entomology

Street address

Faculty of Health, Ghoum University of Medical Sciences, Rohollah Square

City

Ghous
Province
Ghous
Postal code
3711675549
Phone
+98 25 3784 2228
Fax
+98 25 3783 3361
Email
asaghafi@muq.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Kamran Akbarzadeh
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Entomology
Street address
Department of Medical Entomology, School of Public Health, Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
14155-6446
Phone
+98 21 8895 1393
Fax
+98 21 8895 1393
Email
kakbarzadeh@tums.ac.ir
Web page address
<http://tums.ac.ir/faculties/kakbarzadeh>

Person responsible for updating data

Contact

Name of organization / entity
Ghous University of Medical Sciences
Full name of responsible person
Abedin Saghaipour
Position
Ph.D.
Latest degree
Ph.D.

Other areas of specialty/work

Medical Entomology
Street address
Faculty of Health., Ghous University of Medical Sciences, Rohollah Square
City
Ghous
Province
Ghous
Postal code
3711675549
Phone
+98 25 3784 2228
Fax
+98 25 3783 3361
Email
asaghafi@muq.ac.ir
Web page address

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Demographic data including age and gender

When the data will become available and for how long

Starting of sharing one year after case selection.

To whom data/document is available

Data will available for scientists working in academic institutions or people working in businesses can also apply to receive it.

Under which criteria data/document could be used

Using of the shared data will be free for use in academic research.

From where data/document is obtainable

Deputy of Research and Technology of Ghous University of Medical Sciences

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

People who need to have data of this study should write formally to Deputy of Research and Technology of Ghous University of Medical Sciences.

Comments