

# 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 cm<sup>2</sup> 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