

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A clinical trial on efficacy of maggot therapy on *Staphylococcus aureus* and *Pseudomonas aeruginosa* in diabetic foot ulcers

Protocol summary

Summary

Aim of this study is to evaluate the ability of larvae of *Lucilia sericata* in removing of *Staphylococcus aureus* and *Pseudomonas aeruginosa* in diabetic foot ulcers (In-Vivo study). This study has designed as a clinical trial with control group on 50 patients which will refer to wound clinic of Iranian Academic Center for Education, Culture and Research of Tehran University of Medical Sciences. The patients will sign an informed consent before entering the project. Selected patients will divide in half into intervention group and control group. The patients in both groups will take routine treatments while the patients in intervention group will take larval therapy as additional method in healing process. Sampling of bacteria will carry out with sterile swabs in both groups simultaneously. Sampling will continue every 48 hours until removing the bacteria in intervention group. Effects of maggot therapy on bacterial infections in diabetic foot ulcers will clear with analysis of results of sampling. Wound discharges were calculated with weighing of dressings on the wounds before and after use.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060328232N1**

Registration date: **2017-04-02, 1396/01/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-02, 1396/01/13

Registrant information

Name

Kamran Akbarzadeh

Name of organization / entity

School of Public Health, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2017-04-05, 1396/01/16

Expected recruitment end date

2018-04-06, 1397/01/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial on efficacy of maggot therapy on *Staphylococcus aureus* and *Pseudomonas aeruginosa* in diabetic foot ulcers

Public title

Efficacy of maggot therapy on *Staphylococcus aureus* and *Pseudomonas aeruginosa* in diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with at least one diabetic foot ulcer, second degree (based on Wagner); Presence of at least one of two bacteria (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) in the ulcers, patient's age

between 30 to 80; At least seven week post ulceration; having ankle-brachial index (ABI) more than 0.6 or two clear beats on ulcerated leg; not need to be hospitalized; lack of other dangerous diseases; no need for anticoagulant or steroid pharmaceuticals; not addicted to alcohol or opium; no entomophobia; to sign the consent. Exclusion criteria: Having severe diseases such as heart disorders and so on, Severe pain during maggot Therapy, Severe and un-controlled fever during maggot therapy, maceration around the wound after each interval of maggot therapy, Emergent hospitalization during or after of each interval of maggot therapy, Bleeding during maggot therapy

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Block Randomization will use for randomization of the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Ethics in Research of Vice Chancellor of Research, Tehran University of Medical Science

Street address

Enghelab street, Ghods street, Tehran University of Medical Sciences

City

Tehran

Postal code

1416753955

Approval date

2016-05-24, 1395/03/04

Ethics committee reference number

IR.TUMS.REC.1395.2626

Health conditions studied

1

Description of health condition studied

Chronic ulcer of skin, not elsewhere classified

ICD-10 code

L98.4

ICD-10 code description

Chronic ulcer of skin NOS

Primary outcomes

1

Description

Bacterial infections, Staphylococcus aureus and Pseudomonas aeruginosa

Timepoint

sampling before starting of the study and 48 and 96 hours after starting of the study

Method of measurement

culturing of samples in laboratory

Secondary outcomes

1

Description

Amounts of wound secretions

Timepoint

48 and 96 hours after starting of the study

Method of measurement

before/after weighing of dressings of diabetic foot ulcers of both groups, treatment and control, synchronizingly

Intervention groups

1

Description

Patients in intervention group will receive maggot debridement therapy in addition with routine treatment process for healing of diabetic foot ulcers.

Category

Treatment - Surgery

2

Description

Patients in control group will receive routine healing process for healing of diabetic foot ulcers.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Wound Treatment Clinic of Iranian Academic Center
for Education, Culture and Research

Full name of responsible person

Dr. Kamran Akbarzadeh

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Enghaleb street, Felestin street, Nazari avenue, No 17

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research, Tehran University of
Medical Sciences

Full name of responsible person

Mrs Ahadi

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Enghelab street, Ghods Street, Vice Chancellor of
Research, Tehran University of Medical Sciences

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Tehran

Grant name

طرح تحقیقاتی

Grant code / Reference number

95-01-27-30903

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

Yes

Title of funding source

Vice Chancellor of Research, Tehran University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masud Yunesian

Position

Associate Professor - Vice Chancellor of Research of
Tehran University of Medical Sciences

Other areas of specialty/work

Street address

Department of Environmental Health Engineering,
School of Public Health, Tehran University of Medical
Sciences

City

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

PhD - Assistant professor

Other areas of specialty/work

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Dr. Kamran Akbarzadeh

Position

Assistant Professor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty