

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

A clinical trial on efficacy of Biobag (disinfected larvae of *Lucilia sericata* in bag) as new tool in maggot therapy of diabetic foot ulcers

Protocol summary

Summary

Aim of this study is to evaluate the efficacy of Biobag (disinfected larvae of *Lucilia sericata* in bag) as a new tool in maggot therapy of diabetic foot ulcers (In-Vivo study). This study has designed as a clinical trial with control group on 52 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 receive routine treatment of diabetic foot ulcers. Patients in control group will receive maggot therapy beside of routine treatment process. Patients in intervention group will receive Biobag as an additional method in healing process. Measuring of surface of necrotic tissue and granulated tissue will do at a 48 hours interval in both groups. Reducing of necrotic tissues and appearing or increase of granulated tissue will calculate and compare.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017053134272N1**

Registration date: **2017-09-11, 1396/06/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-11, 1396/06/20

Registrant information

Name

Javad Rafinejad

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Tehran University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial on efficacy of Biobag (disinfected larvae of *Lucilia sericata* in bag) as new tool in maggot therapy of diabetic foot ulcers

Public title

Efficacy of Biobag in treatment of diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patient's age between 30 - 80, patients with at least one diabetic foot ulcer, second degree (based on Wagner); 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 sever diseases such as heart disorders and so on, Sever pain during maggot Therapy, Sever 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: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

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

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

1417613151

Approval date

2017-01-25, 1395/11/06

Ethics committee reference number

IR.TUMS.SPH.REC.1395.1533

Health conditions studied

1

Description of health condition studied

Chronic ulcer of skin NOS

ICD-10 code

L98.4

ICD-10 code description

Chronic ulcer of skin, not elsewhere classified

Primary outcomes

1

Description

measuring of 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

measuring of granulated tissue

Timepoint

48 and 96 hours after treatment

Method of measurement

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

Intervention groups

1

Description

Patients in control group will receive maggot therapy beside of routine treatment process.

Category

Treatment - Surgery

2

Description

Patients in intervention group will receive Biobag as an additional method in healing process.

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. Seyyed Mehdi Tabaei

Street address

Enghaleb street, Felestin street, Nazari avenue, No 17

City

Tehran

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

Street address

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

City

Tehran

Grant name**Grant code / Reference number****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**

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Position

Professor

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Web page address

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

