

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

A clinical study on efficacy of maggot therapy for treatment of 3rd grade of burning ulcers

Protocol summary

Study aim

To evaluate the maggot therapy on 3rd burning ulcers on volunteer patients in Shahid Motahhari Hospital of Tehran

Design

A randomized design will conduct in this study. Six possible arrangements of A and B will type on six cards including AABB, ABBA, BBAA, ABAB, BABA, BAAB. All cards will put in a box with shuffling. Dice will select a card for each time of categorizing. After 6 time of categorizing the 24 cases will categorize as control or treatment group. Character A and B will allocate to control and treatment groups respectively.

Settings and conduct

This is a clinical trial study with 56 patients who will refer to Motahhari Hospital. 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: Having at least one burning ulcer (3rd) with bacterial infection, lack of other severe disease such as heart, kidney or lung disorders, no need to use anticoagulants and or steroid pharmaceuticals, no addiction with alcohol or opiums, no entomophobia
Exclusion criteria: Appearing of severe diseases such as heart, kidney or lung disorders, having un-controlled fever, having severe pain and bleeding during treatment.

Intervention groups

Patients entered into the study will assign into two groups, control and intervention. Both groups will take routine treatments for burning ulcers and their related pharmaceuticals. Routine therapy involves local and systemic measures, including surgery, debridement, various kinds of 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

Reducing necrotic tissues and increasing of granulated tissues

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170531034272N2**

Registration date: **2018-07-24, 1397/05/02**

Registration timing: **prospective**

Last update: **2018-07-24, 1397/05/02**

Update count: **0**

Registration date

2018-07-24, 1397/05/02

Registrant information

Name

Javad Rafinejad

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4293 3121

Email address

jrafinejad@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical study on efficacy of maggot therapy for treatment of 3rd grade of burning ulcers

Public title

Efficacy of Maggot therapy on burning ulcers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who have at least one burning ulcer (3rd grade) with bacterial infection. Patients who have not need anticoagulant or steroid pharmaceuticals. Patients who have not acute or other chronic diseases. Patients who have not addicted to alcohol or opium. Patients who have not Osteomyelitis. Patients who have not entomophobia.

Exclusion criteria:

Patients who have sever diseases such as heart disorders and so on during maggot Therapy. Patients who get sever and un-controlled fever during maggot therapy. Patients who have sever pain during maggot Therapy. Patients with maceration around the wound after 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: 24

Randomization (investigator's opinion)

Randomized

Randomization description

A complete randomized design will conduct for categorizing of 24 of volunteer patients into two groups, control and treatment. Six possible arrangements of A and B will type on six cards including AABB, ABBA, BBAA, ABAB, BABA, BAAB. All cards will put in a box with shuffling. Dice will select a card for each time of categorizing. Each time of categorizing will appear the category of four patients to A (for control group) and B (for treatment group. Each card will return to box for next dicing. After 6 time of categorizing the 24 cases will categorize as control or treatment group.

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**

Ethical Committee of Tehran University of Medical Sciences

Street address

Enghelab Street, Ghods Street

City

Tehran

Province

Tehran

Postal code

14155-6446

Approval date

2018-03-04, 1396/12/13

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4691

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

Burning ulcers of grade 3

ICD-10 code

T21-25

ICD-10 code description

Burn and corrosion of trunk, shoulder and upper limb, wrist and hand, hip and lower limb, ankle and foot

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

measuring the necrotic tissues

Timepoint

48 and 96 hours after starting of treatment

Method of measurement

Photographing and measuring by MATLAB 1.6, the mathwork inc, natic, ma, 2000

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

Bacterial infections, Staphilococcus 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: Maggot therapy (use of larvae of *Lucilia sericata*) will use beside of routine therapeutic measures. Routine therapy may be involves local and systemic measures, various kinds of surgery, debridement, various kinds of dressing, nutritional support, and antibiotic and other pharmaceutic therapy. The number of larvae per wound in order to maggot therapy varies depending on the extent and depth of the wound and infection in different parts of the wound. A range of 8 to 10 larvae per cm² of ulcer will use. Interventions will be done every 48 hours. Outcomes of the study (bacterial infections and extend of necrotic and granulated tissues) will be surveyed every 48 hours on the wounds. In this study, the duration of the intervention will be until complete remove of the necrotic tissue.

Category

Treatment - Surgery

2

Description

Control group: Patients of this group will receive routine therapy which may be involves local and systemic measures, various kinds of surgery, debridement, various kinds of dressing, nutritional support, and antibiotic and other pharmaceutic therapy. Outcomes of the study (bacterial infections and extend of necrotic and granulated tissues) will be surveyed every 48 hours on the wounds. In this study, the patients of control group will be under supervisions until complete remove of the necrotic tissue.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mothhari Hospital of Tehran

Full name of responsible person

Mostafa Dah Mardei

Street address

Vali Asr Street, Rashid Yasemi Street

City

Tehran

Province

Tehran

Postal code

--

Phone

+98 21 8877 0031

Fax

Email

m.dahmardehei@gmail.com

Web page address

<http://crtm.iums.ac.ir/fa?sid=49>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraiiian

Street address

Enghelab Street, Ghods Street

City

Tehran

Province

Tehran

Postal code

14155-6446

Phone

+98 21 8163 3698

Fax

+98 21 8163 3686

Email

info@tums.ac.ir

Web page address

<http://vcr.tums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Javad Rafinejad

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Entomology

Street address

Enghelab Street, Ghods Street

City

Tehran

Province

Tehran

Postal code

14155-6446

Phone

+98 21 4293 3121

Fax

+98 21 8895 1393

Email

jrafinejad@tums.ac.ir

Web page address

[https://www.tums.ac.ir/faculties/jrafinejad?lang=en&isplay=mysite](https://www.tums.ac.ir/faculties/jrafinejad?lang=en&display=mysite)

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

1417613151

Phone

+98 21 4293 3111

Fax

+98 21 8895 1393

Email

kakbarzadeh@tums.ac.ir

Web page address

<https://www.tums.ac.ir/faculties/kakbarzadeh?lang=en&style=printfriendly>

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Javad Rafinejad

Position

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 4293 3121

Fax

+98 21 8895 1393

Email

jrafinejad@tums.ac.ir

Web page address

<https://www.tums.ac.ir/faculties/jrafinejad?lang=en&isplay=mysite>

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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

Data and documents about main outcome and secondary outcome

When the data will become available and for how long

starting 3 months after publication

To whom data/document is available

for all involving people

Under which criteria data/document could be used

University teachers and researchers can request data via personal contact and they can use them for their lectures and teaching sessions. Using the data in advertisements and public broadcasting such as printed materials and so on should be arranged formally with Tehran University of Medical Sciences.

From where data/document is obtainable

- from website of Tehran University of Medical Sciences -
- from website of Shahid Motahhari Hospital of Tehran -
- from webpages of involved researchers

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

- Sending email to kakbarzadeh@tums.ac.ir - Sending email to jrafinejad@tums.ac.ir

Comments