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, lake of other sever disease such as heart, kidney or lung disorders, no need to use anticoagulants and or steroid pharmaceutics, no addiction with alcohol or opiums, no entomophobia
Exclusion criteria: Appearing of sever diseases such as heart, kidney or lung disorders, having un-controlled fever, having sever 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 pharmaceutics. 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

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Javad Rafinejad

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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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 pharmaceutics. 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
Ẹnghelab 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

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Person responsible for updating data

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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