

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Investigating the effect of using atmospheric cold plasma radiation to heal wound healing in cutaneous leishmaniasis

Protocol summary

Study aim

Comparison of microbial culture, duration of wound closure, amount of wound exudate over time in the control group, and plasma in patients with salicylic ulcers.

Design

In this study, blinding is done in a two-way blind way. The second phase of the clinical trial is on a group of 142 people, since the list of patients is not known in advance and the number of patients is not known. Every other day, plasma treatment or standard treatment is performed on the patients until A total of 71 subjects were obtained for each treatment. If 71 people are reached in the plasma or standard group, the treatment that has been completed is stopped.

Settings and conduct

one of the treatment groups, i.e. standard treatment alone or standard treatment together with plasma radiation treatment, and we conduct the study in a double-blind manner. Microbial culture will be done from the wounds of all participants at the beginning, the second week of treatment and the end of treatment, then the images will be analyzed with ImageJ software. Hospital of Damghan province

Participants/Inclusion and exclusion criteria

1- Age above 18 years. 2- Not having a history of radiation therapy. 3- Not taking chemotherapy drugs. 4- Not taking drugs that suppress the body's immune system. 5- Not having a severe infection that requires hospitalization. 6- Not having a severe bone infection (Osteomyelitis).

Intervention groups

The standard treatment of Salk includes the injection of glucantim ampoules, and in the second group, i.e., the standard treatment with plasma radiation during 10 alternating sessions, in addition to the standard treatment, the patient's wound is swept with plasma radiation for 2 minutes.

Main outcome variables

Changes in the appearance and size of the wound after plasma processing; Reducing the rate of wound infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160514027888N3**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

Registration date

2023-04-17, 1402/01/28

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2990 4031

Email address

m_khani@sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using atmospheric cold plasma radiation to heal wound healing in cutaneous leishmaniasis

Public title

Cutaneous Leishmaniasis Wound Healing with Cold Plasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No history of radiation therapy. Not taking chemotherapy drugs. Not taking drugs that suppress the immune system. Not having a severe infection that requires hospitalization. Not having a severe bone infection Lack of breastfeeding.

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **142**

Randomization (investigator's opinion)

Randomized

Randomization description

The second phase of the clinical trial is on a group of 142 people since the list of patients is not known in advance and the number of patients is not known. A total of 71 subjects were obtained for each treatment. In case of reaching 71 people in the plasma or standard group, the treatment that has been completed is stopped and the only treatment that still needs patients (71 patients) is performed on people.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the first group, plasma devices are used in the state where the gas flow is on and the patient will feel the gas flow, and in the second group, standard treatment with plasma radiation during 10 alternating sessions, the patient's wound with plasma radiation with a duration of 2 The minute is swept away. The condition of the wound is checked every week during the treatment, and when the wound is completely healed, the treatment is stopped, and the patient's condition will be followed up to one month later.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Basij Boulevard, University of Medical Sciences and Health Services

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2022-10-10, 1401/07/18

Ethics committee reference number

IR.SEMUMS.REC.1401.167

Health conditions studied

1

Description of health condition studied

Cutaneous leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description

Changes in wound area and wound infection rate

Timepoint

Before treatment, after two weeks and at the end of treatment

Method of measurement

Imaging and microbial culture

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The standard treatment of Salk includes injection of glucantim ampoules

Category

Treatment - Drugs

2

Description

Intervention group: Standard treatment along with plasma radiation during 10 alternating sessions

Category

Treatment - Devices

Recruitment centers

1

Recruitment center**Name of recruitment center**

Health center and hospital of Damghan province

Full name of responsible person

Abolfazl Fattah

Street address

after Islamic Azad University, Cheshme Ali Blvd

City

Damghan

Province

Semnan

Postal code

3671637881

Phone

+98 23 3522 5120

Email

Drabolfazlfatah@gmail.com

Web page address

<https://velayathos.semums.ac.ir/>

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Abolfazl Fattah

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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

Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

Abolfazl Fattah

Position

Head of Damghan Province Hospital

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

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Position

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Web page address<https://velayathos.semums.ac.ir><http://facultymembers.sbu.ac.ir/khani/>**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

Yes - There is a plan to make this available

Title and more details about the data/document

Publication of scientific research articles and ISI

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Checking the effectiveness of the treatment process

From where data/document is obtainable

Dr. Mohammad Reza Khani, member of the faculty of Shahid Beheshti University, 09122531497

What processes are involved for a request to access data/documentThe request will be sent via email to m_khani@sbu.ac.ir and will be answered within 30 working days after review.**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Shahid beheshti University

Full name of responsible person

Mohammadreza Khani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Plasma Engineering

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Shahid beheshti University, Velenjak

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1983963113

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