

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigation of the effect of of photodynamic therapy with methylene blue on the treatment of cutaneous leishmaniosis

Protocol summary

Study aim

Investigation of the effect of of photodynamic therapy with methylene blue on the treatment of cutaneous leishmaniosis

Design

Clinical trial with no control group, no blinding and no randomization

Settings and conduct

This study is conducted on 8 patients (4 children and 4 adults) referring to the leishmaniosis clinic of Imam Reza and Ghaem hospitals and Abo-Bargh health center, whose diagnosis is based on the clinical observation of the lesion and positive smear for leishman body. Methylene blue solution is applied topically to the lesion and it is then exposed to a red LED lamp twice a week for 30 minutes for a maximum of 12 weeks. This study will have no blinding and randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: newly diagnosed localized cutaneous leishmaniosis; less than 12 weeks has elapsed since the onset of the lesion; no lesion on face; number of lesions is less than four; no sporotricoid form; size of lesion is less than 5 centimeters; the lesion is not on joints; urban leishmaniosis. Exclusion criteria: pregnancy and breastfeeding; existence of serious or severe underlying diseases.

Intervention groups

Intervention group: In this group, methylene blue solution (50µL of 0.5% MB in water) is applied topically on the lesion (before prescribing methylene blue, if there is a crust in ulcerative lesions, it will be removed by curetting) and after 20 minutes of exposure to LED lamp (Red LED light, with 663 nm wavelength, 100mW / cm²) for 30 minutes, twice a week, for a maximum of 12 weeks.

Main outcome variables

Ulcer development and complete lesion epithelialization in ulcerative lesions; becoming flat and change in induration diameter in non-ulcerative lesions; diameter

of induration and erythema; ulcer size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200803048289N1**

Registration date: **2020-08-31, 1399/06/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-31, 1399/06/10**

Update count: **0**

Registration date

2020-08-31, 1399/06/10

Registrant information

Name

Forough Rakhshanizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2406

Email address

rakhshanizadehf@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-11-05, 1399/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of of photodynamic therapy with methylene blue on the treatment of cutaneous leishmaniasis

Public title

The effect of of photodynamic therapy with methylene blue on the treatment of cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Newly diagnosed localized cutaneous leishmaniasis confirmed by smear Giemsa sample Less than 12 weeks has elapsed since the onset of the lesion No lesion on face Number of lesions is less than four No sporotricoid form Size of lesion is less than 5 centimeters The lesion is not on joints. Urban leishmaniasis (based on patient's clinical observations and regional epidemiology)

Exclusion criteria:

Pregnancy and breastfeeding Existence of serious or severe underlying diseases (such as heart disease, kidney disease, liver disease, immunodeficiency)

Age

From **4 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **8**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-04-29, 1399/02/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.234

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

Ulcer development and complete lesion epithelialization in ulcerative lesions

Timepoint

Before, during and 12 weeks after the end of treatment

Method of measurement

Clinical observations

2

Description

Becoming flat and change in induration diameter in non-ulcerative lesions

Timepoint

Before, during and 12 weeks after the end of treatment

Method of measurement

Clinical observations

3

Description

Diameter of induration and erythema and ulcer size

Timepoint

Before, during and 12 weeks after the end of treatment

Method of measurement

Ruler and caliper

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, methylene blue solution (50µL of 0.5% MB in water) is applied topically on the lesion (before prescribing methylene blue, if there is a crust in ulcerative lesions, it will be removed by curetting) and after 20 minutes of exposure to LED lamp (Red LED light, with 663 nm wavelength, 100mW / cm²) for 30 minutes, twice a week, for a maximum of 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Forough Rakhshanizadeh

Street address

Imam Reza Hospital, next to Imam Reza square, Ibne Sina street

City

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Postal code

9137913316

Phone

+98 51 3802 2406

Email

rakhshanizadehf@mums.ac.ir

2

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Dr. Forough Rakhshanizadeh

Street address

Ghaem hospital, Ahmadabad Blvd

City

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Province

Razavi Khorasan

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91871 45785

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Email

rakhshanizadehf@mums.ac.ir

3

Recruitment center

Name of recruitment center

Ab-o Bargh Health Center

Full name of responsible person

Dr. Forough Rakhshanizadeh

Street address

Ab-o Bargh Health Center, Kuy-e-Ab-o-Barq

City

Mashhad

Province

Razavi Khorasan

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Phone

+98 51 3867 7606

Email

rakhshanizadehf@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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Province

Razavi Khorasan

Postal code

9177899191

Phone

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Email

ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Forough Rakhshanizadeh

Position

Assistance professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Fax**Email**

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

Mashhad University of Medical Sciences

Full name of responsible person

Forough Rakhshanizadeh

Position

Assistance professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Fax**Email**

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Forough Rakhshanizadeh

Position**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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data can be accessible through an email to the corresponding author.

Under which criteria data/document could be used

Data will be available for researchers in universities and other scientific institutes,

From where data/document is obtainable

After sending a request email to the corresponding author, data will be sent in 1 month.

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

Carrying out analysis on data is permitted.

Comments