

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of the effect of liposomal clarithromycin plus glucantime and glucantime in treatment of cutaneous leishmaniasis

Protocol summary

Study aim

Comparison of the effect of liposomal clarithromycin plus glucantime and glucantime in treatment of cutaneous leishmaniasis

Design

A randomized controlled clinical trial with parallel, double-blind, randomized groups

Settings and conduct

The study was carried out at the Leishmania Center in Isfahan. The duration of treatment is 28 days. The patient is given three phalluses, the first one being six weeks after the second treatment, three months later, and the third six months later. Patients were evaluated three times, first by clinical examination and re-epithelization and then by the size of lesions before, 6 weeks, 12 weeks and 6 months after intervention. Patients are not aware of the therapeutic content of others. The data analyzer is also blinded.

Participants/Inclusion and exclusion criteria

Inclusion: Ages 15 to 65 years Skin lesion with a diameter greater than 5 cm Cartilage or articular or facial lesion Number of lesions over 5 in patient Leishmania's disease has been proven by the patient's Smear For Leishman Body Test. Exclusion: Pregnant or lactating patients. History of concurrent or previous treatment for the lesion. Have heart, kidney, liver problems, drug side effects. The patient's unwillingness.

Intervention groups

Control group: Patients with cutaneous leishmaniasis treated with glucantime and placebo for 28 days and three times daily. Intervention group: Patients with cutaneous leishmaniasis, treated with glucantime and liposomal for 28 days and three times a day. For the administration of this drug, the patient is first fully guided and full explanation of how to use the drug in practice is done to the patient. The patient uses liposomal clarithromycin every night. The treatment lasts 28 days.

Main outcome variables

Size of lesion, frequency of lesions, drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038142N17**

Registration date: **2020-03-27, 1399/01/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-27, 1399/01/08**

Update count: **0**

Registration date

2020-03-27, 1399/01/08

Registrant information

Name

Khosro Tavakol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 9134

Email address

tavakol@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of liposomal clarithromycin plus glucantime and glucantime in treatment of cutaneous leishmaniasis

Public title

Comparison of the effect of liposomal clarithromycin plus glucantime and glucantime in treatment of cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 15 to 65 years Skin lesion with a diameter greater than 5 cm Cartilage or articular or facial lesion Number of lesions over 5 in patient Leishmania's disease has been proven by the patient's Smear For Leishman Body Test.

Exclusion criteria:

Pregnant or lactating patients. History of concurrent or previous treatment for the lesion. Have heart, kidney, liver problems, drug side effects. The patient's unwillingness.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **5**

Patients have at least 5 lesions over 5 cm in diameter.

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with leishmania at the Isfahan Leishmania Center who meet the inclusion criteria are selected easily and readily. Then, as long as 60 samples are prepared, sampling continues. Each person with 5 wounds is considered as a block and one intervention (liposomal with glucantime or glucocantime with placebo) is performed. Therefore, there are 6 people in each group. These individuals are divided into control and intervention groups using spss computer program. Subsequently, patients were divided into two groups of 30 patients receiving liposomal clarithromycin with glucantime and glucantime with placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in each group are not aware of the therapeutic content of the other group. Data is also provided to the data analyzer after anonymization.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2019-10-15, 1398/07/23

Ethics committee reference number

IR.MUI.MED.REC.1398.396

Health conditions studied

1

Description of health condition studied

leishmaniasis

ICD-10 code

B55

ICD-10 code description

Leishmaniasis

Primary outcomes

1

Description

The size of the lesion

Timepoint

Before, 6 weeks, 12 weeks and 6 months after intervention

Method of measurement

Physical examination

2

Description

Frequency of waste

Timepoint

Before, 6 weeks, 12 weeks and 6 months after intervention

Method of measurement

Physical examination

3

Description

Drug side effects

Timepoint

6 weeks, 12 weeks and 6 months after intervention

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients with leishmania are treated with glucantime and placebo for 28 days and three times daily. To prescribe this medicine, the patient is first fully instructed and a complete explanation of how the drug is practiced is given to the patient. The patient is given three phalluses, the first one being six weeks after the second treatment, three months later, and the third six months later. Patients were evaluated three times, first by clinical examination and re-epithelization, and then by the size of the lesions before and after treatment.

Category

Placebo

2

Description

Intervention group: For the 30 randomized patients in the intervention group in addition to glucantime, liposomal formulations of topical clarithromycin are provided by dehydration-release. For this purpose, dipalmitoyl phosphatidylcholine (DPPC) and cholesterol in molar ratio of 6 to 1 are used. 114 mg of DPPC and 10 mg of cholesterol are added to a round bottom balloon and dissolved in sufficient chloroform-methanol (2: 1 ratio). The solubility in the rotor is dried and transformed into a thin film. Then 1 mg of clarithromycin is dissolved in 1 ml of phosphate buffer at pH 7.4 and then used to hydrate the lipid film. The resulting suspension is vortexed for 5 minutes and then subjected to ultrasound in a 45 Hz ultrasonic bath for 2 minutes. The resulting suspension is frozen and stored in the refrigerator when used. To prescribe medication, the patient is first fully instructed and a complete explanation of how the drug is practiced is given to the patient. The patient uses liposomal clarithromycin every night. The duration of treatment is 28 days. The patient is given three phalluses, the first one being six weeks after the second treatment, three months later, and the third one 6 months later. Patients were evaluated three times, first through clinical examination and re-epithelization and then the size of the lesions that were photographed before and after treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin and Leishmaniasis Research Center

Full name of responsible person

Atusa Hakami Fafd

Street address

Sadiqah Tahereh Comprehensive Rehabilitation and Medical Center, after Shahidan intersection, Khorram street.

City

Isfahan

Province

Isfahan

Postal code

81747-73461

Phone

+98 31 3668 0048

Email

a.hakamifard@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Street address

Vice-Chancellor for Research of School of Medicine,. Isfahan University of Medical Sciences,. Hezar Jarib Ave.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Reza Radmehr

Position

Consultant

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

Street address

Isfahan University of Medical Sciences, Hazar Jarib
Street

City

Esfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8597

Fax

+98 31 3668 8597

Email

mehrradreza1@Yahoo.Com

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

Esfahan University of Medical Sciences

Full name of responsible person

Atusa Hakami Fafd

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Al-Zahra Hospital, Sofah Boulevard.

City

Esfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

a.hakamifard@med.mui.ac.ir

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

Esfahan University of Medical Sciences

Full name of responsible person

Neda Abrishami

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Biostatistics

Street address

Isfahan University of Medical Sciences, Hazar Jarib
Street

City

Esfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8597

Fax**Email**

dadepardaz2005@gmail.com

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

The information is shared two years after the results are published.

When the data will become available and for how long

The information is shared two years after the results are published.

To whom data/document is available

Specialists and assistants in the infectious and dermatology department

Under which criteria data/document could be used

Compare this medicine with another medicine

From where data/document is obtainable

Send mehrradreza1@Yahoo.Com an email

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

Send mehrradreza1@Yahoo.Com an email

Comments

