Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Oct 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

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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
Isfehan
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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
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
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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
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