Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessment of the efficacy of Gentian violet accompanied with cryotherapy in the treatment of old world cutaneous leishmaniasis

Protocol summary

Summary

The study is designed to compare the efficacy of topical gentian violet accompanied with cryotherapy and cryotherapy alone in the treatment of cutaneous leishmaniasis. The study is a randomized, single-blind, controlled with standard treatment, unicenter, phase II clinical trial. Inclusion criteria include clinical diagnosis of cutaneous leishmaniasis and confirmation of diagnosis by direct smear or Polymerase chain reaction test. Exclusion criteria include pregnancy or Lactation, history of consumption of topical or systemic anti-leishmania medications or cryotherapy in the recent 1 month before enrolling in study, patients with more than 10 lesions, patients with lesions lasting more than 4 months, and lesions on the cartilages (Ear or nose). The patients were selected by convenient sampling from cutaneous leishmaniasis patients referred to dermatology clinic of Faghihi hospital in Shiraz and 60 patients were enrolled in the study. The patients were divided into two groups with 25 patients in each by block randomization. Intervention group applied gentian violet 1% ointment two times a day for 8 weeks besides weekly cryotherapy and control group underwent cryotherapy alone once weekly for 8 weeks. Primary outcome measures was clinical cure defined as reduction in lesion size which was assessed in the 4th, and 8th week of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071316557N2**
Registration date: **2017-08-13, 1396/05/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-13, 1396/05/22

Registrant information

Name
Mozhdeh Sepaskhah
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Research grant number 94-01-01-9107 of Research Council of Shiraz University of Medical Sciences

Expected recruitment start date

2015-10-02, 1394/07/10

Expected recruitment end date

2016-02-29, 1394/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the efficacy of Gentian violet accompanied with cryotherapy in the treatment of old world cutaneous leishmaniasis

Public title

Effect of Gentian violet ointment and cryotherapy on cutaneous leishmaniasis treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Clinical diagnosis of cutaneous leishmaniasis; Confirmation of diagnosis by direct smear or Polymerase chain reaction test Exclusion criteria: Pregnancy or Lactation; History of consumption of topical or systemic anti-leishmania medications or cryotherapy in the recent 1 month before enrolling in study; Patients with more than 10 lesions; Patients with lesions lasting more than 4 months; Lesions on the cartilages (Ear or nose)

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand St., Shiraz. Iran

City
Shiraz

Postal code

Approval date
2015-06-10, 1394/03/20

Ethics committee reference number
IR.SUMS.med.REC.1394.29

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
Clinical cure

Timepoint
4th and 8th weeks of the study

Method of measurement
complete response defined as more than 75% reduction, partial response defined as 50%–75% reduction, and no response to treatment defined as less than 50% reduction in the size of the lesion compared with baseline. Size is measured by multiplying the longest and shortest diameters of the lesion.

Secondary outcomes

1

Description
Side effects

Timepoint
8th week of the study

Method of measurement
Asking the patient

Intervention groups

1

Description
Intervention: Applying gentian violet 1% ointment twice daily for 8 weeks besides liquid nitrogen cryospray cryotherapy weekly for 8 weeks

Category
Treatment - Drugs

2

Description
Control: Only liquid nitrogen cryospray cryotherapy weekly for 8 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dermatology clinic, Shahid Faghihi hospital

Full name of responsible person
Kasra Behdad

Street address
Dermatology clinic, Faghihi hospital, Zand St., Shiraz,

Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

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Shiraz

Grant name

Grant code / Reference number

94-01-01-9107

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

Yes

Title of funding source

Research Council of Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Kasra Behdad

Position

Resident

Other areas of specialty/work

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty