Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of Topical Sertaconazole Efficacy with Cryotherapy versus Cryotherapy with placebo in Treatment of Cutaneous Leishmaniasis

Protocol summary

Study aim
Evaluation of the effect of topical Sertacanazole plus cryotherapy in the treatment of cutaneous leishmaniasis and its comparison with cryotherapy with placebo

Design
Randomized controlled clinical trial, with two parallel groups, double blind,

Settings and conduct
Both types of cream were packed in 30 g coded and similar encoded packets and were provided to patients by an expert who did not know the type of patient.

Participants/Inclusion and exclusion criteria
Entry requirements include men and women at least 12 years of age, less than 3 lesions, lesions less than 3 cm, positive leishmania smear and less than 4 months of laceration. Exit conditions include infectious lesions, longevity for more than 4 months, facial lesions, anti-leishmaniasis in the past month and allergic to sertanoconazole.

Intervention groups
Patients taking medication (Sertacanazole) and patients taking placebo (cold cream)

Main outcome variables
Area of Cutaneous leishmaniasis lesion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180623040195N1**
Registration date: **2018-08-01, 1397/05/10**
Registration timing: **retrospective**

Last update: **2018-08-01, 1397/05/10**
Update count: **0**

Registration date
2018-08-01, 1397/05/10

Registrant information

Name
Farideh Jowkar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3212 5592

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jowkarf@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-11-21, 1395/09/01

Expected recruitment end date
2017-01-20, 1395/11/01

Actual recruitment start date
2016-11-21, 1395/09/01

Actual recruitment end date
2017-01-20, 1395/11/01

Trial completion date
empty

Scientific title
Evaluation of Topical Sertaconazole Efficacy with Cryotherapy versus Cryotherapy with placebo in Treatment of Cutaneous Leishmaniasis

Public title
Evaluation of Topical Sertaconazole Efficacy with Cryotherapy versus Cryotherapy with placebo in Treatment of Cutaneous Leishmaniasis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients above 12 years old Numbers of lesions are less than 3 Diameter of the lesions are less than 3 cm Positive smear for leishmaniasis Less than 4 months from

the onset of the lesion

Exclusion criteria:

Pregnant and lactating women Unwillingness to participate in the study Known cases of systemic diseases

Age

From **12 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided into two groups including drug (A) and placebo (B) using Random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both types of cream were packed in 30 g coded and similar encoded packets and were provided to patients by an expert who did not know the type of patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2016-06-29, 1395/04/09

Ethics committee reference number

IR.SUMS.med.REC.1395.6131

Health conditions studied

1

Description of health condition studied

Cutaneus Leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description

Area of the lesion

Timepoint

The 0, 2, 4 and 8 weeks

Method of measurement

Using the rule and measurement of the diameters of lesion

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For these patients, once a week, cryotherapy was performed, for the maximum duration of 8 weeks and used Sertaconazole QD for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: For these patients, once a week, cryotherapy was performed, for the maximum duration of 8 weeks and used cold cream QD for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Shahid Faghihi Hospital

Full name of responsible person

Dr. Farideh Jowkar

Street address

Shahid Faghihi Hospital, Zand street

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Seyed Basir Hashemi
Street address
Shiraz University of medical Sciences, Research vice, Zand Street
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7134814336
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hashemib@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Farideh Jowkar
Position
Associate Professor
Latest degree
Specialist
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

Demographic data and the result of the clinical trial

When the data will become available and for how long

6 month later

To whom data/document is available

Researchers

Under which criteria data/document could be used

After publication of the extracted article of the clinical trial

From where data/document is obtainable

Sending Email to the researchers

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

Sending the request via the email

Comments