

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Email address

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**

Cutaneous 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  
**City**  
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7134814336  
**Phone**  
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**Email**  
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**  
Dermatology  
**Street address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Associate Professor  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Latest degree**  
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**Email**

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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**