Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the efficacy of topical sodium chlorite gel with intralesional injection of glucantime to cryotherapy with intralesional injection of glucantime for the improvement of lesions in patients with cutaneous leishmaniasis

Protocol summary

Study aim

Our purpose in this study is to evaluate the therapeutic effect of topical sodium chlorite gel as an affordable and low-cost treatment on cutaneous leishmaniasis .

Design

48 patients with cutaneous leishmaniasis participate in a phase 3, two arm parallel, non randomized clinical trial with control group.

Settings and conduct

The size of the largest diameter of cutaneous leishmaniasis lesions of patients referred to the dermatology clinic of Shahid Faghihi Hospital in Shiraz is recorded. The control group is treated with cryotherapy for two consecutive cycles for 20 seconds with a margin of 2 mm and injection of glucantime into the lesion by Sanofi of France as a standard treatment on a weekly basis. Lesions In the case group, weekly glucantime injections are performed in a similar manner. 0.045% sodium chlorite gel is given to patients for topical use once a day under a closed dressing. Patients are examined weekly for wound size, induration, and possible side effects.

Participants/Inclusion and exclusion criteria

Patients with cutaneous leishmaniasis referred to the hospital dermatology clinic whose skin smear test is positive for the leishmaniasis parasite, if they are over 18 years old, have no immunodeficiency, lack of pregnancy and lactation, have a maximum of 3 lesions less than 5 Cm are included in the study,if they are satisfied.

Intervention groups

Leishmaniasis lesions in the control group patients are treated with weekly injections of glucantime and cryotherapy, and in the case group patients with weekly injections of glucantime and daily use of topical sodium chlorite gel. The size of the lesions, the possible side effects of each treatment, and the healing process of the lesions are carefully recorded.

Main outcome variables

The rate of reduction in the size of the lesions and the overall recovery are compared in both treatments. Complications of both treatments are recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190714044200N2**
Registration date: **2020-10-02, 1399/07/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-02, 1399/07/11**
Update count: **0**

Registration date

2020-10-02, 1399/07/11

Registrant information

Name

Amir Miri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date
2020-11-21, 1399/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of topical sodium chlorite gel with intralesional injection of glucantime to cryotherapy with intralesional injection of glucantime for the improvement of lesions in patients with cutaneous leishmaniasis

Public title
The effect of topical sodium chlorite gel in treatment of cutaneous leishmaniasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients over 18 years of age with cutaneous leishmaniasis A maximum of 4 months have passed since the onset of cutaneous leishmaniasis in patients.
Exclusion criteria:
Immunodeficient individuals Cutaneous leishmaniasis on the face of patients Pregnancy and lactation Patients with more than 3 lesions of cutaneous leishmaniasis Patients with lesions greater than 5 cm in diameter Patients with concomitant mucosal lesions Patients who have received systemic or topical anti-leishmaniasis medication in the last 4 weeks.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not 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
Headquarters Of Shiraz University of Medical Sciences - Zand St - Shiraz
City
Shiraz
Province
Fars
Postal code
34786-71946
Approval date
2018-10-15, 1397/07/23
Ethics committee reference number
IR.SUMS.MED.REC.1397.284

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
Measuring the diameter of cutaneous leishmaniasis lesions in patients
Timepoint
At the beginning of the study, one week later, two weeks later, three weeks later, four weeks after starting treatment
Method of measurement
Measuring ruler

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Topical treatment with sodium chlorite is done in such a way that 0.045% sodium chlorite gel is prepared by the hospital pharmacist and is given to patients in 200 gr containers and they are asked to use this drug daily at the wound site. And put a closed dressing on it. Repeat the next day after washing the

wound with serum or with mild soap and water. Treatment with intralesional injection of glucantime according to the national guidelines for the treatment of cutaneous leishmaniasis with a fine needle number 27 or 30 at an angle of 45 degrees so that the tip of the needle is up and the center of the lesion, in the border of healthy skin and induction begins And 0.1 cc of the drug is injected into the dermis so that the margin of the lesion becomes white. This operation is repeated at intervals of 1 cm in the entire margin of the lesion and throughout the lesion. In large lesions and provided that the lesion center is not injured, 0.1 to 0.2 cc of drug is injected in the lesion center. This injection is given weekly until the end of the trial. The type of glucantime ampule used is the type imported by the Ministry of Health. Glucantime 1.5 gr / 5 CC is a product of the French company SANOFI.

Category

Treatment - Drugs

2

Description

Control group: In this group, treatment with intralesional injection of glucantime according to the national guidelines for the treatment of cutaneous leishmaniasis with a fine needle number 27 or 30 at an angle of 45 degrees so that the tip of the needle is up and the center of the lesion, in the border of healthy skin and induction begins And 0.1 cc of the drug is injected into the dermis so that the margin of the lesion becomes white. This operation is repeated at intervals of 1 cm in the entire margin of the lesion and throughout the lesion. In large lesions and provided that the lesion center is not injured, 0.1 to 0.2 cc of drug is injected in the lesion center. This injection is given weekly until the end of the trial. The type of glucantime ampule used is the type imported by the Ministry of Health. Glucantime 1.5 gr / 5 CC is a product of the French company SANOFI. Cryotherapy is done weekly by a dermatologist. The device manufactured by the company Iran Sarma darman is used and The chemical substance used in this method is a liquid nitrogen with temperature of -198. Each cryotherapy session is performed for two 20-second freezing cycles and a 60 second thawing cycle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic, Shahid Faghih Hospital of Shiraz University of Medical Sciences

Full name of responsible person

Amir Miri

Street address

Zand Blvd, Shahid Faghihi Hospital, Dermatology Department office

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7134846114

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Email

miria@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Younes Ghasemi

Street address

Headquarters Of Shiraz University of Medical Sciences - Zand Blvd

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3478671946

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ghasemiy@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

Amir Miri

Position

Resident of dermatology

Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Department of Dermatology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Amir Miri
Position
Resident of dermatology
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Amir Miri
Position
Resident of dermatology
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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miria@sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information and data from the research: Information on the main outcome.
When the data will become available and for how long
Start the access period 6 months after printing the results.
To whom data/document is available
Researchers working in academic institutions.
Under which criteria data/document could be used
Information on the main outcome in the form of correspondence with researchers.
From where data/document is obtainable
Dermatology Department, Shiraz university of medical sciences.
What processes are involved for a request to access data/document
After applying to the office of the Department of Dermatology of Shiraz University of Medical Sciences, this request is sent to the university's vice chancellor. If the information is agreed upon, it is provided to the applicant. The approximate duration of this process is one week.

Comments