Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The effect of topical cream containing processes of Chelidonium majus and hyoscyamus niger with propolis on leishmaniasis : Randomized and double-blind clinical trial

Protocol summary

Study aim
The effect of topical cream containing Chelidonium majus and Hyoscyamus niger with propolis on the improvement of Cutaneous leishmaniasis

Design
The randomized clinical trial that in the first phase, it will be interventional and have a control group, and it will be double-blind. In phase 2, blinding is not done and the drug is given to the patient as the main drug.

Settings and conduct
A double-blind study on 150 patients with cutaneous leishmaniasis is carried out in several centers under the 3rd group of Kashan University of Medical Sciences and Isfahan Medical Sciences and the Health Vice-Chancellor of Esfrain Medical School in North Khorasan.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Patients aged at least 12 years of both sexes 2- Positive leishmania smear Exclusion criteria: 1- Pregnancy and breast feeding 2- Number of lesions over ten

Intervention groups
Intervention group: The intervention group includes 150 patients with cutaneous leishmaniasis. Topical cream containing 0.5 grams of Chelidonium majus and 0.5 grams of Hyoscyamus niger along with 2 grams of propolis is used for three weeks. The duration of the use of each cream will be 7 days and the treatment will be done once a day. The patient receives a maximum of 3 creams during the treatment period. Control group: The control group includes 150 patients with cutaneous leishmaniasis. Topical treatment with amphotericin b used for three weeks. The duration of the use of each cream will be 7 days and the treatment will be done once a day. The patient receives a maximum of 3 creams during the treatment period. amphotericin b is prepared and provided to the patients in the same tube as the intervention group.

Main outcome variables
Measuring the diameter of lesion induration using a caliper

General information

Reason for update
Completion of the first phase and the second phase of the study

Acronym

IRCT registration information
IRCT registration number: **IRCT20200516047462N5**
Registration date: **2022-04-12, 1401/01/23**
Registration timing: **prospective**

Last update: **2023-09-17, 1402/06/26**
Update count: **3**

Registration date
2022-04-12, 1401/01/23

Registrant information

Name
morteza kosari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2023-01-21, 1401/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of topical cream containing processes of Chelidonium majus and hyoscyamus niger with propolis on leishmaniasis : Randomized and double-blind clinical trial

Public title
The effect of Chelidonium majus and hyoscyamus niger with propolis on cutaneous Leishmaniasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged at least 12 years of both sexes Positive leishmania smear Real time PCR
Exclusion criteria:
Pregnancy and breastfeeding The number of lesions more than 10
Age
From **12 years** old to **85 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
The sample is divided into two groups using the Terminated Block Randomization method with blocks of 4 and 6. Prescription drugs (intervention and control) are determined based on this method and a special number is assigned to them. The doctor and the patient do not know about receiving the drug or placebo. Codes have been recorded on the worm and only the epidemiologist as one of the plan's executors knows about it. In the second phase of the study, the doctor knows the type of prescription and the patients are randomly entered into the study, and the topical cream as the main drug will be compared with routine drugs. The first phase of the study is double blind and the second phase of the study is unblinded.
Blinding (investigator's opinion)
Double blinded
Blinding description
Intervention and control creams (Amphotericin B cream) are completely the same in terms of shape and container size. These creams also have no differences in terms of color and are completely unrecognizable. The important point is that the patient is told, which this topical cream used for patient may be a medicine or a control medicine. In blinding, both the doctor and the patient will be blinded.
Placebo
Used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
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Approval date
2022-02-09, 1400/11/20
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1400.199

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
Complete healing of the lesion
Timepoint
On arrival or day zero, 2, 4, 7, 14 and 21 days after treatment
Method of measurement
Based on measuring the diameter of the induration of the lesion using a caliper

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group includes 75 patients with cutaneous leishmaniasis. Topical cream containing 0.5 grams of Chelidonium majus and 0.5 gr of Hyoscyamus niger along with 2 gr of propolis is used for three weeks. The duration of the use of each cream will be 7 days and the treatment will be done once a day. The patient receives a maximum of 3 creams during the treatment period.

Category
Treatment - Drugs

2

Description
Control group: The control group includes 75 patients with cutaneous leishmaniasis. Topical treatment with amphotericin b used for three weeks. The duration of the use of each cream will be 7 days and the treatment will be done once a day. The patient receives a maximum of 3 creams during the treatment period. Amphotrypsin b is prepared and provided to the patients in the same tube as the intervention group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital of Kashan
Full name of responsible person
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2

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4

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Full name of responsible person
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Sponsors / Funding sources

1

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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
Kashan University of Medical Sciences
Proportion provided by this source
10
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
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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
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 about participants such as age, gender, level of education and employment will be reported. The treatment protocol and the duration of treatment process will be reported. Therapeutic results of the product and possible side effects will be reported.

When the data will become available and for how long
The start of the access period will be 6 months after patent presentation or 12 months after article publication.

To whom data/document is available
The data will be available to researchers working in academic and scientific institutes.

Under which criteria data/document could be used
The data printed in the article is accessible.

From where data/document is obtainable
Moderator: Morteza Kosari Email address: kosarimorteza12@gmail.com

What processes are involved for a request to access data/document
We will try to respond to researchers as soon as possible.

Comments