Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Preparation and characterization of two-layer dressing based on nanofiber/ hydrogel containing royal jelly and propolis extract and determining its therapeutic effect on skin lesions caused by Leishmania major in human (Clinical trial – Phase 1).

Protocol summary

Study aim

- Preparation and characterization of a two-layer dressing based on nanofiber/hydrogel containing royal jelly and propolis extract and determination of its therapeutic effect on skin lesions caused by Leishmania major (Phase 1 clinical trial in humans) compared to standard treatment with glucantim - Achieving an effective and cost-effective combination for the treatment of cutaneous leishmaniasis with limited side effects and easier application (topical)

Design

Random selection with organizational support, consent collection, documentation of disease and prescriptions, assignment to treatment/control groups, parasite burden assessment post-treatment via parasitological and molecular methods, and follow-up.

Settings and conduct

A randomized clinical trial with a factorial group design of 44 patients in four groups, enrolled between November 2025 and December 2026, and followed for one year

Participants/Inclusion and exclusion criteria

Inclusion: Consent for treatment, presence of Leishman bodies, age 15–45, active open lesions (size/number), Iranian citizenship, Leishmania major infection.
Exclusion: Pregnancy, breastfeeding, immunodeficiency, underlying diseases, old/recurrent or atypical lesions, prior leishmaniasis or treatment, lesions in sensitive areas (e.g. eyelid), allergy to honey products, use of immunosuppressants, regional adenopathy.

Intervention groups

Groups: Combined dressing (topical): royal jelly + propolis + external chitosan nanofiber coating - Hydrogel dressing + external chitosan nanofiber coating - Dressing with chitosan nanofiber - Control: Treatment with Glucantime (injection)

Main outcome variables

Switching from injectable to topical drug delivery using advanced technologies to target Leishmania major lesions more effectively, aiming for faster healing and scar-free (cosmetic) outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241013063352N1**
Registration date: **2025-06-20, 1404/03/30**
Registration timing: **prospective**

Last update: **2025-06-20, 1404/03/30**
Update count: **0**

Registration date

2025-06-20, 1404/03/30

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-10-22, 1404/07/30

Expected recruitment end date

2026-10-22, 1405/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preparation and characterization of two-layer dressing based on nanofiber/ hydrogel containing royal jelly and propolis extract and determining its therapeutic effect on skin lesions caused by Leishmania major in human (Clinical trial – Phase 1).

Public title

The effect of a two-layer dressing based on nanofiber/hydrogel containing royal jelly and propolis extract on the treatment of cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1- Individual consent and initial agreement to continue treatment 2- Examination of the presence of Leishmaniasis in the lesion using conventional sampling methods and microscopic confirmation 3'- Individuals between the ages of 15-45 4- Active open lesions including ulcers (for 3 to 6 months) and the size of the ulcer is less than 5 cm 5- Number of skin lesions (maximum three to four lesions per patient) 6- Iranian citizen 7- The causative agent is Leishmania major.

Exclusion criteria:

Pregnant women People with immunodeficiency and underlying diseases and high-risk individuals People with old lesions (more than 5 months) or infected and recurrent People who have previously been treated with anti-leishmanial drugs Previous history of leishmaniasis Atypical forms of the disease and purulent lesions Presence of wounds or lesions in sensitive areas such as the eyelids History of allergy to honey products Users of immunosuppressive drugs Regional adenopathy

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **44**

More than 1 sample in each individual

Number of samples in each individual: **3**

3 noticeable and easy-to-reach wounds in each person

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize individuals (44 people) into 4 treatment groups, the following procedure is followed: Patients selected from Tehran and Isfahan medical centers are prepared according to the entry and exit criteria. A list of 44 eligible patients is prepared and numbered from 1 to 44. Then, using a random number table, a number between 1 and 44 is selected for each patient. The names of the 4 treatment methods are placed on 4 similar envelopes and placed in a bag. From these 4 envelopes, one envelope is extracted from the bag and assigned to the selected patient. Whenever the number of individuals in a group, which is 11 (based on their type of treatment), is complete, the envelope related to that treatment is removed and the next envelope is taken out of the bag and completed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

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District 6,Pour Sina St. Qods St. Enghelab St. Tehran, Iran P94V+8MF.

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Postal code

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Approval date

2025-04-12, 1404/01/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1404.034

Health conditions studied

1

Description of health condition studied

Zoonotic cutaneous leishmaniasis

ICD-10 code

L08.89

ICD-10 code description

Other specified local infections of the skin and subcutaneous tissue

Primary outcomes

1

Description
The improvement rate and reduction of skin lesions caused by Leishmania major using the designed dressing.

Timepoint
Measurement of the wound and the presence of parasites in the lesion before treatment, one month, three months, and six months after treatment

Method of measurement
Measuring the dimensions of the lesion with calipers, taking a sample, and examining the presence of parasites using molecular methods (Real time PCR) at the lesion site.

Secondary outcomes

1

Description
Possibility of causing skin sensitivity and inflammatory reactions, no scarring after the lesion heals

Timepoint
During treatment and after the lesion heals

Method of measurement
Inflammatory response test (cytokine measurement), careful observation of the site of the previous lesion for the presence or absence of scarring

Intervention groups

1

Description
Control group: Standard treatment with Glucantime (injection) - Positive control: Intralesional injection in 4 areas around the wound to the extent that the wound area turns white (1-2 ml) - once a week for 3 to 5 weeks

Category
Treatment - Drugs

2

Description
Intervention group 1: Combined dressing group including royal jelly and propolis and external coating of chitosan nanofiber (topical). The external coating consists of chitosan nanofiber with low molecular weight. Hydrogel dressing prepared with 10% gelatin and 20% concentration of propolis hydroalcoholic extract and 10% concentration of royal jelly dissolved in water are used as the internal coating of the dressing. This dressing should be changed every 24 hours. The treatment time is about one month.

Category
Treatment - Drugs

3

Description
Intervention group 2: Hydrogel dressing group with external chitosan nanofiber coating (topical): This group is similar to intervention group 1 but does not contain royal jelly and propolis hydroalcoholic extract. The hydrogel dressing is prepared with 10% gelatin and acts as the inner coating of the dressing. This dressing should also be changed every 24 hours. The treatment time is about one month.

Category
Treatment - Drugs

4

Description
Intervention group 3: Chitosan nanofiber dressing group (external coating of the studied dressing - topical) - In this group, chitosan with low molecular weight nanofibers is prepared (with an electrospinning device) and is placed on the Leishmania wound as an external coating without any other material (fixed with a bandage). The approximate treatment time is about one month.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Center for Research and Training in Skin Diseases And Leprosy- Tehran University of medical sciences

Full name of responsible person
Dr. Alireza Firooz

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No. 415, corner of Naderi St. (former Sohail), Shahid Taleghani St., Tehran

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Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Zoonoses Research Center (Common Human and Animal Diseases), Tehran 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
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
Undecided - It is not yet known if there will be 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
After the completion of the research, only the general data of the patients, the main results and consequences are expressed. The detailed information about the project participants will not be provided individually.

When the data will become available and for how long
6 months after publication of the article

To whom data/document is available
The data of this research can be useful for medical sciences, pharmacy, phytopharmacology, cosmetic-beauty industry, Center for disease control and Accident and Burn centers.

Under which criteria data/document could be used
The use of this research information is permitted for those who intend to synthesize similar products and conduct human trials (provided that the product manufacturing protocol is not copied) on other diseases. Access to patient information is permitted only for information on the status of the disease and the percentage of recovery (with reference).

From where data/document is obtainable
To contact the Project Managers: Dr. Mohsen Mahmoudi - Dr. Mehdi Mohabali Telephone: 0098-21-88951392 Mobile: 09130967538 Email address: mmahmoudi45@gmail.com

What processes are involved for a request to access data/document
If the applicant is from Iran, she/he can send his request via email and within one to two weeks, the application file will be sent if possible. This period is relatively time-consuming for people outside Iran and may take three to four weeks. In Iran, it can also be done in person at the Faculty of Health, Tehran University of Medical Sciences, Parasitology Department.

Comments