Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of leech therapy on the severity and extent of psoriasis lesions compared to conventional medical treatments in psoriasis patients

Protocol summary

Study aim
Determining the effectiveness of leech therapy on the recovery period of psoriasis in patients referred to Shahid Faqihi Hospital and Amirul Mominin Burn Hospital in Shiraz in 1402-1403

Design
The researcher will refer to the dermatology department of the mentioned hospitals and 60 patients will be selected using the available sampling method based on the entry and exit criteria. And then they will be randomly assigned to intervention and control groups in parallel with the help of Random Generator Software. Demographic information checklist and PASI evaluation checklist will be filled for both groups. Intervention group patients will be taught about leech therapy and how to do the work. The study will be double-blind

Settings and conduct
The study site is Shahid Faqihi Hospital and Amirul Mominin Hospital of Shiraz University of Medical Sciences The statistical consultant and evaluator knew which patients belong to the control group and which belong to the intervention group in all phases of the study

Participants/Inclusion and exclusion criteria
inclusion criteria: Age 60-20, not suffering from other skin disorders, having symptoms of psoriasis, not allergic to leeches, willingness to participate in the study exclusion criteria: Pregnancy and breastfeeding, not wanting to continue studying, not following the treatment process and not attending meetings regularly Taking vitamin K, E, C, herbal supplements such as garlic, ginger, ginkgo, ginseng compounds, aspirin, dipyridamole, clopidogrel, heparin, warfarin and non-steroidal anti-inflammatory drugs

Intervention groups
Intervention group: (leech therapy): The intervention will be carried out for 5 weeks, with a time interval of 7 days, by placing 10 leeches in the psoriasis area, in addition to routine care. Control group: routine care only

Main outcome variables
The intensity of the psoriasis area, the size of the psoriasis area

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230821059210N1**
Registration date: **2023-09-24, 1402/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-24, 1402/07/02**
Update count: **0**

Registration date
2023-09-24, 1402/07/02

Registrant information

Name
Ehsan Khavare

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 5433 0851

Email address
khavareehsan58@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of leech therapy on the severity and extent of psoriasis lesions compared to conventional medical treatments in psoriasis patients

Public title

The effectiveness of leech therapy on the healing period of psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age 20-60, Absence of other skin disorders Having symptoms of psoriasis Insensitivity to leech

Exclusion criteria:

Failure to attend meetings regularly Failure to follow the treatment process Pregnancy and breastfeeding Not using vitamins K, E, C, herbal supplements such as garlic, ginger, ginkgo, ginseng compounds, aspirin, dipyridamole, clopidogrel, heparin, warfarin and non-steroidal anti-inflammatory drugs.

Age

From **20 years** old to **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After going to the departments of both hospitals and getting the list of patients from them, the patients will be contacted and interested people will be registered. Then, from the obtained list, 60 people will be randomly selected into the random number table, and with the help of the Random Number Generator software, out of 60 people (numbers 1-60), 30 people will be randomly assigned to the intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

1- The statistical expert will be unaware of the intervention and control group. He will not be told whether the data is from the intervention or control group. Rather, only the groups will be marked with numbers 1 and 2 or with A-B, so only the researcher knows and he can interpret the results. 2- The nurses providing routine care and the person collecting data at the end of the study will also be blinded. That is, they will not know which patient was in the intervention group and which patient was in the control group. Patients are given codes and only the researcher knows these codes

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jahrom University of Medical Sciences

Street address

motahari street

City

jahrom

Province

Fars

Postal code

7414846199

Approval date

2023-07-29, 1402/05/07

Ethics committee reference number

034.IR.JUMS.REC.1402

Health conditions studied

1

Description of health condition studied

psoriasis

ICD-10 code

psoriasis

ICD-10 code description

L40.0

Primary outcomes

1

Description

Severity and extent of psoriasis

Timepoint

Before and after the intervention in both intervention and control groups

Method of measurement

Before and after the intervention by the index of the extent and severity of psoriasis by a specific checklist Psoriasis Area Severity Index (PASI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The amount of PASI will be checked before the start of the study. Then, for 5 weeks, with a time interval of 7 days, it will be done by placing 10 leeches in the affected area. Before using the leech, the leech will be kept in non-chlorinated water for 24 hours, and before sticking the leech, the target area will be washed with water and odorless soap. Then, wearing gloves, the leech will be removed. In order to prevent the irritation and irritation of the leech. At first, 10 leeches are placed in the infected areas and the leech treated area is observed and examined for 2 minutes (to check that the leech sticks and sucks blood). If the leech is able to stick and no blood sucking, with a needle, a small incision will be made in the area and the leech will be placed on that area. Then a wet gauze or a transparent plastic cup will be placed on it to provide moisture to the leech's body and prevent the leech from moving. During the leech treatment, the patient will be checked for bleeding, sensitivity, removal of the leech, movement and vital signs of the patient. After sucking the blood by the leech, the leech will either be removed by itself or it can be removed by pouring a few drops of alcohol or betadine. and in order to prevent the possible transmission of infection by leech, it should be destroyed by pouring alcohol. After each leech treatment session, the patient will be checked for the amount of bleeding and stabilization of vital signs, and if there is no problem, he will be discharged. Before the start of the study and after the end of leprosy therapy, the PASI level of the patients in both groups will be checked. It is worth noting that the patients will receive common psoriasis treatments during the study.

Category

Treatment - Other

2

Description

Control group: They receive common and standard psoriasis treatments, and before and after the intervention in the intervention group, a checklist to determine the severity and extent of psoriasis is completed for them.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

SHahid fagihi shiraz

Full name of responsible person

Amirreza Dehghanian

Street address

Shiraz - Karim Khan Zand Boulevard - in front of Shahid Faqihi Street (Rosutgar) - next to the medical school

City

Shiraz

Province

Fars

Postal code

۷۱۳۴۸۴۶۱۱۴

Phone

+98 71 3212 5400

Email

ADehghan@Sums.ac.ir

Web page address

https://faghihi.sums.ac.ir/page-FgPresidency/fa/34/form/pId1445

2

Recruitment center

Name of recruitment center

Amir al-Momenin Hospital, Shiraz

Full name of responsible person

Mohammad Mehdi Aslani

Street address

Shiraz, km 2 of Sadra Road, Amirul Mominin Burn Accident and Rehabilitation Hospital

City

Shiraz

Province

Fars

Postal code

۷۱۹۸۷۵۳۸۵۴

Phone

+98 71 3614 6100

Email

amiralmomeninbh@sums.ac.ir

Web page address

https://amiralmomeninbh.sums.ac.ir/page-amiralmomeninhp/fa/32/form/pId1363

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Kavoss solhjo

Street address

Jahrom - Ostad Motahari St. - after the Nursing Faculty - Jahrom University of Medical Sciences - campus site

City

Jahrom

Province

Fars

Postal code

۷۴۱۴۸۴۶۱۹۹

Phone
+98 71 5434 0409

Email
Pazhuheshi@jums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Jahrom 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
Jahrom University of Medical Sciences

Full name of responsible person
Mohsen fasele

Position
assisstant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Jahrom Motahari Street. University campus site. nursing school

City
jahrom

Province
Fars

Postal code
7414846199

Phone
0098 71 5433001

Email
m.fasele@jums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Mohsen fasele

Position
assisstant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Jahrom Motahari Street. University campus site. nursing school

City
Jahrom

Province
Fars

Postal code
7414846199

Phone
0098 71 5434001

Email
m.fasele@jums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Mohsen fasele

Position
assisstant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Jahrom Motahari Street. University campus site. nursing school

City
jahrom

Province
Fars

Postal code
7414846199

Phone
0098 71 5433001

Email
m.fasele@jums.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
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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Send the request to the responsible author's email, and if necessary, the information will be available for meta-analysis

From where data/document is obtainable

09177924361 Mohsen fasele

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

Send the request to the responsible author's email, and if necessary, the information will be available for meta-analysis

Comments