Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation of the safety and efficacy of Artemisia herbal cream product for the improvement and treatment of psoriasis skin patients

Protocol summary

Study aim

The effect of cream containing Artemisia plant extract on psoriasis patients.

Design

This study is a placebo-controlled randomized double-blind clinical trial, and its target population is 30 patients aged 15 to 50 with psoriasis who refer to a specialist. After making creams containing artemisia extract and creams containing Clobetasol (the main drug) and comparing the organoleptic characteristics of both types of creams, including color and smell, the creams were packed in a completely similar package and one person outside the study Creams containing artemisia extract or cream Clobetasol-containing drugs are assigned one of two codes, A or B.

Settings and conduct

The herbal cream is 60 grams in the form of a tube and contain herbal extract. The way to use Artemisia cream is that the patient is asked to apply an index finger size amount of cream on the knee lesion with dimensions of 5x10 square centimeters or a lesion with an area of about 50 square centimeters every night for 3 weeks. The doctor has specified and marked, put it on and leave it until the morning, and during this time do not use any other topical or non-topical anti-psoriasis products. Then it is evaluated based on the PASI criteria.

Participants/Inclusion and exclusion criteria

Psoriasis patients; 15 to 50 years old who are able to use the topical product; Personal willingness to cooperate in the plan and complete the written informed consent form.

Intervention groups

Intervention and control groups. Each patient is given the main drug (Clobetasol cream) and the study drug (cream containing Artemisia extract), which is assigned one of the codes A or B in the blinding section.

Main outcome variables

redness of psoriasis rash; PASI number corresponding to each patient means the intensity index of the psoriasis area; The thickness and prominence of psoriasis rashes; flaking; level of conflict

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001157N20**
Registration date: **2023-03-29, 1402/01/09**
Registration timing: **prospective**

Last update: **2023-03-29, 1402/01/09**
Update count: **0**

Registration date

2023-03-29, 1402/01/09

Registrant information

Name

Hasan Fallah Huseini

Name of organization / entity

Institute of Medicinal Plants

Country

Iran (Islamic Republic of)

Phone

+98 26 3476 4010

Email address

fallah@imp.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the safety and efficacy of Artemisia herbal cream product for the improvement and treatment of psoriasis skin patients

Public title

The effect of Artemisia herbal cream product on improving the symptoms of patients with psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with psoriasis. 15 to 50 years old who are able to use the topical product. Personal desire to participate in the project and the signing of a written consent.

Exclusion criteria:

People who are allergic to plant extracts and Artemisia annua plant extract. pregnant women. Lactating women. Patients treated for systemic psoriasis 3 months before and during the study. Patients who have a history of malignant disease, taking anti inflammatory and immunosuppressive drugs.

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment to intervention and control groups. A random number table and block randomization method is used. In this method 60 eligible patients are assigned into 30 blocks of 2 patients. Then, each of the 2 patients in the block is randomly assigned to take herbal cream or standard cream, so that 30 patients assigned to each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

After making creams containing artemisia extract and creams containing Clobetasol (the main drug) and comparing the organoleptic characteristics of both types of creams, including color and smell, the creams were packed in a completely similar package and one person outside the study Creams containing artemisia extract or creams containing Clobetasol are assigned one of the two codes A or B so that the patients, the project managers, the specialist doctor and the person in charge of data analysis do not know about the content of creams A or B during the study. .

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics Committees of Islamic Azad University, Shahrood Branch

Street address

Islamic Azad University, Shahrood Branch

City

Shahrood

Province

Semnan

Postal code

3619943189

Approval date

2023-02-15, 1401/11/26

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1401.073

Health conditions studied

1

Description of health condition studied

Psoriasis

ICD-10 code

L40.0

ICD-10 code description

Psoriasis vulgaris

2

Description of health condition studied

Other psoriasis

ICD-10 code

L40.8

ICD-10 code description

Other psoriasis

3

Description of health condition studied

Moderate to severe psoriasis

ICD-10 code

L40.1

ICD-10 code description

Generalized pustular psoriasis

Primary outcomes

1

Description
Erythema (redness) of Psoriasis rashes.
Timepoint
At the beginning of the study (before the start of the intervention) and after three weeks (end of the study).
Method of measurement
Observation.

2

Description
PASI number suitable for each patient (severity index of the psoriasis area)
Timepoint
At the beginning of the study (before the start of the intervention) and after three weeks (end of the study).
Method of measurement
The software for calculating the severity index of psoriasis area version 2.7.1

3

Description
The thickness and prominence of psoriasis rashes.
Timepoint
At the beginning of the study (before the start of the intervention) and after three weeks (end of the study).
Method of measurement
Observation.

4

Description
Flaking.
Timepoint
At the beginning of the study (before the start of the intervention) and after three weeks (end of the study).
Method of measurement
Observation.

5

Description
level of conflict.
Timepoint
At the beginning of the study (before the start of the intervention) and after three weeks (end of the study).
Method of measurement
Ruler (cm).

6

Description
Intensity of itching.
Timepoint
At the beginning of the study (before the start of the intervention) and after three weeks (end of the study).
Method of measurement
Using a visual scale with scoring by patients from 0 (no itching) to 10 (the most severe itching).

7

Description
Patient satisfaction.
Timepoint
After completing the study.
Method of measurement
VAS index (visual analog scale) which is a 10-point scale and shows the quality of the patient in the form of quantity with numbers.

Secondary outcomes

1

Description
Side effects of the drug.
Timepoint
During the study.
Method of measurement
Questionnaire and specialized visit by a dermatologist.

Intervention groups

1

Description
Intervention group: for 3 weeks, the patients of this group used a 60-gram tube of plant extract cream containing artemisia extract, wheat germ oil, jojoba oil, avocado oil, and pomegranate seed oil every night for 3 weeks. They use it locally on the lesions specified by the doctor.
Category
Treatment - Drugs

2

Description
Control group: The patients of this group use the cream containing Clobetasol topically on the lesions specified by the doctor, every night for 3 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital of Shahrood
Full name of responsible person
Marjan Talebi
Street address
Imam Hossein Hospital., End Imam street.,
City
Shahrood
Province
Semnan

Postal code
3616951835
Phone
+98 23 3234 2000
Fax
+98 23 3233 3902
Email
marjan.talebi@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Sahebali Manafi
Street address
Shahrood University blvd, Islamic Azad University, Shahrood branch
City
Shahrood
Province
Semnan
Postal code
3619943189
Phone
+98 23 3239 4279
Email
ali_manafi2005@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Nasrin Razavianzadeh
Position
Internal Medicine
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
University Blvd, Khatam al-Anbia hospital
City
Shahrood
Province
Semnan
Postal code
3619943189
Phone
+98 23 3223 1442
Fax
+98 23 3233 1876
Email
nasrinrazavianzadeh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Homapharmed Company
Full name of responsible person
Mohammadreza Gholibeikian
Position
R & D
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No. 26, Nader Alley, North Jamalzadeh St, Enghelab Square
City
Tehran
Province
Tehran
Postal code
1418635643
Phone
+98 21 6276 9000
Fax
+98 21 6690 8071
Email
mgholibeikian@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
University of Golestan
Full name of responsible person
Amirhosein Firouzi
Position
Ph.D candidate of Phytochemistry
Latest degree
Ph.D.
Other areas of specialty/work
Isolation and purification of natural products, herbal medicine
Street address

Shahid Beheshti St, Golestan university

City

Gorgan

Province

Golestan

Postal code

15759-49138

Phone

32254168 – 32254164 – 32254163 - 017

Fax

+98 17 3222 9068

Email

Amirhosein.firouzi@gmail.com

Web page address

https://scholar.google.com/citations?user=NRiPoyUAAAAJ&hl=en

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

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

No - There is not a plan to make this available

Analytic Code

No - There is not 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

Research results are published in the form of articles.

When the data will become available and for how long

The article will be published about six months after the completion of the project.

To whom data/document is available

There is no objection or prohibition for public use of the published article.

Under which criteria data/document could be used

The use of data with reference to the source is unrestricted.

From where data/document is obtainable

Nasrin Razavianzadeh University Blvd, Khatam al-Anbia hospital with 1000 Patient Beds, Shahrood Postal code: 3619943189 Phone: 09121731846 Email: nasrinrazavianzadeh@gmail.com

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

To view the report of this research, after sending the request, the Vice Chancellor for Research of Islamic Azad University, Shahrood branch will follow up and inform.

Comments