# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

27 May 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**