

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Studying the efficacy of a Topical formulation based on Aloe vera, Salix alba and Persea americana on relieving Psoriasis symptoms

Protocol summary

Study aim

Studying the efficacy of a topical formulation containing aloe vera, white willow and avocado on relieving psoriasis symptoms

Design

Clinical trial without control group, unblinded, in phase 2 on 15 patients

Settings and conduct

Phase 2 clinical trials of efficacy and safety in 15 patients with mild to moderate psoriasis including men and women aged 19 to 59 years after their deliberate consent the exact location of the lesion is examined in constant certain light and camera conditions. Then the itching and burning rate of the selected lesions is graded from 0 to 10 by the patient. (0: no pain and itching (pruritis) and 10: maximum itching and burning) and psi score of the lesion is determined and recorded by the researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria: male or female volunteers with mild to moderate psoriasis patients between 19 and 59 years old healthy physical condition with deliberate consent
Exclusion criteria: having any systemic disease that affects the skin-using any topical or oral product to treat psoriasis in the last 4 weeks-using moisturizers during the study-any chemicals such as solvents contact during the study without informing the researchers-patients suffering cancer-pregnant and lactating women

Intervention groups

Main outcome variables

Changing in pruritis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160306026938N9**

Registration date: **2021-11-12, 1400/08/21**

Registration timing: **prospective**

Last update: **2021-11-12, 1400/08/21**

Update count: **0**

Registration date

2021-11-12, 1400/08/21

Registrant information

Name

Mahdi Vazirian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6412 1223

Email address

vazirian_m@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the efficacy of a Topical formulation based on Aloe vera, Salix alba and Persea americana on relieving Psoriasis symptoms

Public title

Effect of Aloe vera, white willow and avocado on relieving psoriasis symptoms

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with mild to moderate psoriasis Healthy physical condition Patient's deliberate consent

Exclusion criteria:

Having any systemic disease that affects the skin Using any topical or oral product to treat psoriasis in the last 4 weeks Using moisturizers during the study Any chemicals such as solvents contact during the study without informing the researchers Patients suffering cancer Pregnant and lactating women

Age

From **19 years** old to **59 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qods street corner, Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-10-20, 1400/07/28

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.800

Health conditions studied

1

Description of health condition studied

Psoriasis

ICD-10 code

L40

ICD-10 code description

Psoriasis

Primary outcomes

1

Description

The level of burning and itching

Timepoint

2 and 4 weeks after receiving the medicine

Method of measurement

patient questionnaire and psi score

Secondary outcomes

1

Description

PSI score

Timepoint

At the beginning of the intervention and then, 2 and 4 weeks after receiving the medicine

Method of measurement

measurement of the erythema, scaling and induration of the skin

Intervention groups

1

Description

Intervention group: Intervention group: the patient will use the topical gel twice daily on affected areas.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center of Research and Training in Skin Diseases and Leprosy

Full name of responsible person

Dr. Saman Ahmad Nasrollahi

Street address

No. 415, Nader Ave. corner, Taleghani Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice-chancellor of research and technology
Street address
Central organization of Tehran university of medical sciences, corner of Ghods Ave., Keshavarz
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rmo@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
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

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahdi Vazirian
Position
PhD of Pharmacognosy
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data would be accessible in related dissertation

When the data will become available and for how long

The onset of access from 2021

To whom data/document is available

everyone

Under which criteria data/document could be used

The documents could be accessible in case of further experiments

From where data/document is obtainable

Iran, Tehran, Tehran University of Medical Sciences, Faculty of Pharmacy, Dr. Mahdi Vazirian

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

Personal request

Comments