Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effects of neem oil (Azadirachta Indica)in improving the skin manifestations of psoriasis vulgaris patients

Protocol summary

Study aim

This study aims to investigate the effects of neem oil (Azadirachta indica) on improving skin manifestations in patients with psoriasis vulgaris at Baqiyatallah Hospital.

Design

This is a randomized controlled clinical trial (RCT) with a 1:1 allocation ratio. Randomization is performed using block randomization with block size of 4. To reduce bias, the data analyst and outcome assessor will be blinded to treatment allocation.

Settings and conduct

This study is conducted at the Skin and Beauty Clinic of Baqiyatallah Hospital in Tehran. After screening and confirming eligibility criteria, patients are enrolled after obtaining informed consent and randomly assigned to one of two groups. Outcome assessments are performed at baseline, one month, and two months after treatment initiation.

Participants/Inclusion and exclusion criteria

Participants are adults aged 18 years or older with mild to moderate psoriasis vulgaris. Exclusion criteria include: presence of other skin diseases, nail involvement in psoriasis, use of neuropsychiatric medications (lithium, beta-blockers, hydroxychloroquine), concurrent use of systemic or biological treatments for psoriasis, and known allergy to neem oil.

Intervention groups

This study includes two groups: the control group (17 patients) receiving standard treatment with topical betamethasone 0.05% twice daily for 2 months, and the intervention group (17 patients) receiving standard treatment plus neem oil applied once daily topically to affected areas for 2 months.

Main outcome variables

The primary outcome is the change in Psoriasis Area and Severity Index (PASI) score before and after intervention. Secondary outcomes include changes in Dermatology Life Quality Index (DLQI) and patient satisfaction measured using a 5-point Likert scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260215068870N1**
Registration date: **2026-04-22, 1405/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2026-04-22, 1405/02/02**
Update count: **0**

Registration date

2026-04-22, 1405/02/02

Registrant information

Name

Parsa ghorbanpourkhamse

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4442 4155

Email address

parsaghorbanpour1379@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-04-20, 1405/01/31

Expected recruitment end date

2026-07-27, 1405/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of neem oil (Azadirachta Indica)in improving the skin manifestations of psoriasis vulgaris patients

Public title
Neem oil in psoriasis vulgaris
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults (18 years or older) diagnosed with psoriasis vulgaris Patients with mild to moderate psoriasis
Exclusion criteria:
Presence of other skin diseases Nail involvement in psoriasis Use of neuropsychiatric medications such as lithium or drugs like beta-blockers and hydroxychloroquine Concurrent use of systemic or biological treatments for psoriasis Presence of other significant skin diseases Known allergies or sensitivities to neem oil
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization using four-block permutations with random order will be employed. In this method, treatment blocks are randomly arranged forward and backward. For example, with a block length of 4 and two treatment groups, the following permutations are possible: ABBB, ABAB, ABBA, BABA, BAAB, BBAA. By randomly combining these blocks, a balanced randomization list of the two treatment groups is obtained.
Blinding (investigator's opinion)
Double blinded
Blinding description
To reduce bias in this clinical trial, the blinding process is designed as follows: Data Analyst Blinding: After data collection, information regarding patient grouping (intervention or control group) will be removed from the database and replaced with numerical codes. The data analyst will work exclusively with numerical codes and will remain unaware of patient treatment allocation. The code-to-treatment group mapping table will be maintained by the principal investigator, and codes will be revealed only after completion of the initial statistical analysis. Outcome Assessor Blinding: Assessment of primary outcomes (PASI index, DLQI questionnaire, and patient satisfaction) will be performed by an individual who is not involved in the randomization process or patient treatment. This assessor is not aware of the treatment group assigned to each patient, and assessments are conducted without knowledge of group allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Sciences
Street address
Baqiyatallah University of Medical Sciences, Mollasadra Street, Vanak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۳۵۹۱۵۳۸۱
Approval date
2026-02-02, 1404/11/13
Ethics committee reference number
IR.BMSU.BAQ.REC.1404.142

Health conditions studied

1

Description of health condition studied
Psoriasis vulgaris
ICD-10 code
L40.0
ICD-10 code description
Psoriasis vulgaris

Primary outcomes

1

Description
Psoriasis Area and Severity Index (PASI)
Timepoint
Three time points: 1-Before treatment initiation (Baseline) 2-One month after treatment start 3-Two months after treatment start
Method of measurement
Clinical assessment by a dermatologist using the standard PASI index form. Scoring is based on four body regions (head/neck, trunk, upper extremities, lower extremities) and three parameters (erythema, induration, scaling) considering the percentage of

involved area.

2

Description
Dermatology Life Quality Index (DLQI)
Timepoint
Three time points: 1-Before treatment initiation (Baseline) 2-One month after treatment start 3-Two months after treatment start
Method of measurement
Completion of the standard DLQI questionnaire by the patient. Each question has 4 responses (0-3) with a maximum total score of 30. Higher scores indicate lower quality of life.

3

Description
Patient's satisfaction level
Timepoint
Three time points: 1-Before treatment initiation (Baseline) 2-One month after treatment start 3-Two months after treatment start
Method of measurement
Using a 5-point Likert scale:1 = Completely dissatisfied2 = Dissatisfied3 = Neutral4 = Satisfied5 = Completely satisfied

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group, in addition to standard treatment (topical betamethasone 0.05% corticosteroid), use pure neem oil (Azadirachta Indica) once daily topically on psoriatic lesions.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group topical betamethasone 0.05% corticosteroid (twice daily for 2 months) topically on psoriatic lesions.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Skin and Beauty Clinic, Baqiyatallah Hospital Outpatient Clinic
Full name of responsible person
Dr. Majid Shohrati (Professor, Project Supervisor)
Street address
Skin and Beauty Clinic, Baqiyatallah Hospital, Mollasadra Street, Vanak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 917 228 2616
Email
majidshohrati@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Abbas Ali Imanifouladi
Street address
Baqiyatallah University of Medical Sciences, Mollasadra Street, Vanak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۳۵۹۱۵۳۸۱
Phone
+98 21 8804 0060
Email
abasaliimanifooo@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person

Dr. Majid Shohrati

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
Baqiyatallah hospital, Mollasadra Street, Vanak, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 917 228 2616

Email
majidshohrati@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Dr. Majid Shohrati

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
Baqiyatallah hospital, Mollasadra Street, Vanak, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 917 228 2616

Email
majidshohrati@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Parsa Ghorbanpourkhamse

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

Street address
No. 24, Banafshe 7 Street, Eastern Laleh Street, South Janatabad, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 21 4442 4155

Fax

Email
Parsaghorbanpour1379@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
Yes - There is a plan to make this available

Title and more details about the data/document
Clinical Trial Data: The collected data includes patient demographic data (age, gender), Psoriasis Area and Severity Index (PASI) scores at baseline, one month, and two months after treatment initiation, Dermatology Life Quality Index (DLQI) questionnaire, patient satisfaction scores using Likert scale (1-5), information regarding underlying diseases and family history of psoriasis. After de-identification, fully anonymized individual-level data will be available for sharing.

When the data will become available and for how long
Access Period Start: 12 months after completion of data collection and publication of final study results. Considering the 2-month implementation period, data access is expected to be available from late 2026. Data will be accessible to applicants for 5 years after initial publication.

To whom data/document is available
All researchers employed in accredited academic and research institutions, researchers in pharmaceutical and cosmeceutical industries, graduate students (Master's and PhD) in dermatology and pharmacy-related fields, and dermatology specialists may request access to anonymized data. Applicants must state a clear purpose for data use.

Under which criteria data/document could be used
- Data may only be used for research purposes (including meta-analysis, secondary studies, and validation of findings). - Commercial use requires a separate agreement and prior notification. - Permitted analyses

include descriptive, comparative, and statistical modeling analyses. - Applicants must properly cite the original study in any publications derived from these data. - Any re-analysis must be approved by the relevant ethics committee.

From where data/document is obtainable

To obtain the data or documents, applicants may contact Dr. Majid Shahrati (Principal Investigator) at phone number +98-21-82483388 or by mail at: Tehran, Baqiyatallah Hospital, Faculty of Pharmacy, Clinical Research Development Unit. After registration of the clinical trial in the IRCT system, the email address and study website will also be announced through the system. Telephone contact is recommended as the first and fastest method of communication.

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

The request process begins with applicants submitting a written request including their research purpose, research proposal, and confidentiality agreement. The principal investigator will then review the request and announce the decision within 3 weeks (1 week for initial review and 2 weeks for final decision). If approved, a data use agreement will be sent, and after signing, the data will be provided within 1 week. Overall, the entire process from request submission to data receipt takes approximately 4-5 working weeks.

Comments