

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

A prospective randomized double blinded clinical trial comparing a series of herbal oils (Alnovat) with calcipotriol and vehicle in mild plaque psoriasis

Protocol summary

Summary

The purpose of this study is to compare efficacy of combination of herbal oils (Alnovat) with calcipotriol 50mcg/g cream and placebo in control of dermal manifestations of mild psoriasis vulgaris in adult patients. 135 patients will be included in this prospective, multi center, 3-arm parallel group, randomized, double blinded, 12-week study. Inclusion criterion is adult patients with diagnosis of plaque-psoriasis. Exclusion criteria are body surface affected more than 10%; any type of psoriasis treatment in last 4 weeks; background of taking medicines which are known to potentially trigger psoriasis; subjects with a hypersensitivity to creams; women who are pregnant, breast feeding or have the intention of becoming pregnant within the next 12 weeks; patients suffering from other types of psoriasis; diagnosed chronic disease including but not restricted to any kind of cancer, HIV-AIDS, any kind of viral and/or bacterial demagogical disease and eczema; previous dermal disease subsequent to systemic disease such as SLE, dermatomyositis and etc. All eligible subjects will be randomly assigned into either of three groups: Group A: Vehicle (control); group B: Alnovat; group C: Calcipotriol. The patients will be instructed to apply the medication to the affected skin twice daily for 12 consequent weeks. The primary outcome measure is the PASI, which will be calculated at weeks 0, 2, 4, 8 and 12. The efficacy outcome is the change in PASI score from baseline to the measure at 12 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205209800N1**

Registration date: **2012-12-08, 1391/09/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-12-08, 1391/09/18

Registrant information

Name

Parvin Mansouri

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6659 5911

Email address

mansorip@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

ALNAPHARM GmbH & Co.KG

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A prospective randomized double blinded clinical trial comparing a series of herbal oils (Alnovat) with calcipotriol and vehicle in mild plaque psoriasis

Public title

Effect of Alnovat in psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion/Exclusion: Diagnosed plaque-psoriasis with a body surface affected less than 10%;Treatment naive with either topical and/or systemic medications and/or phototherapy in last 4 weeks before enrolment in the study; No background of taking medicines which are known to potentially trigger psoriasis including beta blockers, lithium and antimalarial drugs; Willing to participate in the study considering the visit requirements; Able to read, understand and sign patient informed consent.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Science and Health Service

Street address

Central administration of university, Ghodss St., Keshavarz Blvd

City

Tehran

Postal code

1417653761

Approval date

2012-05-02, 1391/02/13

Ethics committee reference number

91-01-150-17691-51861

Health conditions studied**1****Description of health condition studied**

Psoriasis vulgaris

ICD-10 code

L40.0

ICD-10 code description

Plaque psoriasis

Primary outcomes**1****Description**

PASI score

Timepoint

Baseline,weeks2,4,8,12

Method of measurement

Inspection

Secondary outcomes**1****Description**

Added at 2015-04-19: 1-Number of Patients who reached PASI 75 and PASI 50 at any time during the study. or 2- Adverse events of Alnovat during topical administration in adult patients with mild plaque psoriasis

Timepoint

Added at 2015-04-19: at any time during the study

Method of measurement

Added at 2015-04-19: PASI Score

Intervention groups**1****Description**

Use of vehicle 2 times per day on all plaques for 12 continuous weeks

Category

Placebo

2**Description**

Use of calcipotriol cream 50mg/g 2 times per day on all plaques for 12 continuous weeks

Category

Treatment - Drugs

3**Description**

Use of Alnovat Cream 2 times per day on all plaques for 12 continuous weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Skin clinic of Imam Khomeini hospital
Full name of responsible person
Dr Parvin Mansouri
Street address
Keshavarz Blvd.
City
Tehran

2

Recruitment center

Name of recruitment center
Skin clinic of Dr Mansouri
Full name of responsible person
Dr Parvin Mansouri
Street address
No.458,Mahan building,Yousefabad St.
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
ALNAPHARM GmbH & Co.KG
Full name of responsible person
Ali Nahavandi
Street address
No2,Nargess alley, Narenjestan St., Farmanyeh
City
Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

ALNAPHARM GmbH & Co.KG

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran Univeristy of Medical Science

Full name of responsible person

Dr Parvin Mansouri

Position

Full professor

Other areas of specialty/work

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Contact

Name of organization / entity

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty