Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Email address

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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 calcipoteriol 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
Street address
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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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