Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of the efficacy of Indigo Naturalis ointment in the treatment of Plaque – type Psoriasis and comparison between ointments made of two different Chinese and Iranian herbs and betamethasone ointment

Protocol summary

Summary

Psoriasis is an inflammatory chronic disease, which is characterized with erythemato plaques on the body surface. Its incidence is estimated about 1-3%. Indigo Naturalis is a herbal pigment which has been commonly used for the treatment of inflammatory dermatitis and dermatoses in Chinese Medicine. This pigment could be extracted from 5 Chinese herbs among them, Indigofera tinctoria is available in Iran. The aim of this study is to evaluate the therapeutic effect of Indigo Naturalis out of Baphicacanthus cusia (made in China) on psoriasis in comparison to the ointment out of Indigofera tinctoria (made in Iran) and Betamethasone . Patients with plaque type psoriasis will be selected regarding the inclusion and exclusion criteria. Patients will be randomly divided into three groups (Betamethasone, Iranian product of Indigofera tinctoria, Chinese form of Indigo Naturalis). PASI score will measured before the treatment, at week 2, 4, 6 and 8.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512157265N5**
Registration date: **2016-04-16, 1395/01/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-16, 1395/01/28

Registrant information

Name

Hoda Azizi

Name of organization / entity

Mashhad University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Deputy of Research of Mashhad University of Medical Sciences

Expected recruitment start date

2015-12-23, 1394/10/02

Expected recruitment end date

2016-05-09, 1395/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the efficacy of Indigo Naturalis ointment in the treatment of Plaque – type Psoriasis and comparison between ointments made of two different Chinese and Iranian herbs and betamethasone ointment

Public title

Study of the efficacy of Indigo Naturalis ointment in the treatment of Plaque – type Psoriasis and comparison between ointments made of two different Chinese and Iranian herbs and betamethasone ointment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 12 years old and more; chronic

plaque psoriasis; lesion extension less than 10% body surface area, bilateral lesions on the extremities; do not have another important diseases, especially liver and kidney diseases. Exclusion criteria: use of topical drugs in the last 14 days or systemic drug in the last 30 days; pregnancy or a plan to get pregnant, breast-feeding; people with hepatitis B and C and HIV positive patients; allergy to herbal medicines; abnormal laboratory findings; use of topical or systemic drugs that have a positive or negative effect on progression of the disease.

Age
From **12 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
MUM's central office, Daneshgah street, Mashhad

City
Mashhad

Postal code

Approval date
2009-09-09, 1388/06/18

Ethics committee reference number
87691

Health conditions studied

1

Description of health condition studied
Psoriasis

ICD-10 code
L40

ICD-10 code description
Psoriasis

Primary outcomes

1

Description
PASI score

Timepoint
Before treatment, week 2, week 4, week 6, week 8

Method of measurement
Comparison between ointments made of two different Chinese and Iranian herbs and betamethasone ointment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Treatment by Chinese ointment of Indigo Naturalis containing 20% Indigo Naturalis (produced by Tongrentang Pharmaceutical company, Beijing, China) and 80% vehicle (25% Vaseline, 30% yellow wax, and 45% olive oil); topical treatment twice a day for 8 weeks

Category
Treatment - Drugs

2

Description
Intervention group 2: Treatment by Iranian ointment containing 20% Indigofera tinctoria extract (Plant powder with 70% ethanol) and 80% vehicle (25% Vaseline, 30% yellow wax, and 45% olive oil); topical treatment twice a day for 8 weeks

Category
Treatment - Drugs

3

Description
Control group: Topical treatment by betamethasone ointment 0.1%+ Edible dyes twice a day for 8 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dermatology clinic and Dermatology and Leishmaniasis Research Center

Full name of responsible person
Dr. Mohammad Javad Yadanpanah

Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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MUM's central office, Daneshgah street, Mashhad
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Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
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

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Person responsible for updating data

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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