

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 erythematous 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 be 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

Full name of responsible person

Dr Mohsen Tafaghodi

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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****Contact****Name of organization / entity**Department of Chinese and complementary medicine,
Mashhad University of Medical Sciences**Full name of responsible person**

Dr Hoda Azizi

Position

MD, PhD in Accupuncture, Assistant Professor

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Web page address<http://www.skinhealth.ir>**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*