

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of TNF α Levels in Psoriatic Plaque Tissue after topical St Johns Wort (*Hypericum perforatum* L) Application in Patients with Plaque Type Psoriasis vulgaris

Protocol summary

Summary

Psoriasis is an inflammatory disorder formed by inappropriate interaction of T lymphocytes with keratinocytes and consequent eruption of immune responses which leads to keratinocytes hyper-proliferation and epidermis thickening and scaling. TNF- α is known to be a key cytokine in psoriasis pathogenic process. *Hypericum perforatum* is known to have both anti-inflammatory and anti-proliferative properties and has been reported to be clinically helpful in management of psoriatic lesions. A randomized, double-blind, placebo-controlled study of topical *hypericum perforatum* was conducted on 40 patients with mild to moderate plaque type psoriasis. *Hypericum perforatum* ointment was applied to one side of the body and placebo ointment to the other side twice daily for 4 consecutive weeks. Modified psoriasis area severity index (PASI) scores and histological and clinical changes were investigated after topical application of *hypericum perforatum* and compared with placebo application. Moreover, TNF- α level in tissue samples were measured with immunohistochemistry method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503173106N24**
Registration date: **2015-05-03, 1394/02/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-03, 1394/02/13

Registrant information

Name

Farshad Hashemian

Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

Country

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University, Pharmaceutical Sciences Branch (IAUPS)

Expected recruitment start date

2011-02-17, 1389/11/28

Expected recruitment end date

2015-05-05, 1394/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of TNF α Levels in Psoriatic Plaque Tissue after topical St Johns Wort (*Hypericum perforatum* L) Application in Patients with Plaque Type Psoriasis vulgaris

Public title

The Effects of Topical St Johns Wort Application in Patients with Plaque Type Psoriasis vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with the age between 18 to 50 years old; diagnosis of mild to moderate plaque type psoriasis on both sides of the body; not being under medical treatment for the past two months. Exclusion criteria: pregnancy; lactation; suffering from a major illness (such as cardiovascular disease, acute renal or liver disease, cancer or active malignancy); not having plaque psoriasis on both sides of the body.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University, Pharmaceutical Sciences
Branch (IAUPS)

Street address

No.99 Yakhchal Street, Shariati Avenue, 1941933111,
Tehran, Iran.

City

Tehran

Postal code

1941933111

Approval date

2010-09-27, 1389/07/05

Ethics committee reference number

7173

Health conditions studied

1

Description of health condition studied

Plaque Psoriasis

ICD-10 code

L40.0

ICD-10 code description

Psoriasis vulgaris

Primary outcomes

1

Description

Erythema, Thickness, Scaling

Timepoint

At the end of week 4

Method of measurement

Modified psoriasis area severity index (PASI) scores

2

Description

Tissue TNF α Level

Timepoint

At the end of Week 4

Method of measurement

Mouse anti-human TNF α (28401.111) monoclonal antibody

Secondary outcomes

1

Description

Side effects

Timepoint

At the end of week 4

Method of measurement

Questionnaire, Photography, Scoring

Intervention groups

1

Description

Herbal ointment containing 5% Hypericum perforatum extract in Vaseline base was used on lesions of one side of the body twice daily.

Category

Treatment - Drugs

2

Description

Placebo ointment in Vaseline base was used on the lesions of the other side of the body twice daily.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Parvin Mansouri

Street address

Keshavarz blv, Imam Khomeini Hospital complex

City

Tehran

Fax**Email**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University, Pharmaceutical Sciences Branch, Faculty of Pharmacy (IAUPS)

Full name of responsible person

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Position

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Islamic Azad University, Pharmaceutical Sciences Branch

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**

Islamic Azad University, Pharmaceutical Sciences Branch, Faculty of Pharmacy

Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Pharm.D.

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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