

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

A double blind, placebo controlled study of standardized hydro-alcoholic extract of *Curcuma longa* on plaque psoriasis

Protocol summary

2013-06-11, 1392/03/21

Summary

Psoriasis is an autoimmune and recurrent chronic inflammatory skin disease that influenced by both genetic and triggers factors. About 1-3% of the world's populations regardless of their age are affected. The characteristic features are hyperproliferation of keratinocytes leading to redness, thickening and scaling of epidermis followed with itching and appearance of the lesions which in most cases bother the patients medically and psychologically. Psoriasis is treated with the wide ranges of oral and topical medications; however, major side effects are associated with these agents. Therefore, we were prompted to target this well known herbal agent with fantastic safety profile to be formulated as a novel topical micro emulsion. Prior to the formulation, the hydro alcoholic extract of turmeric rhizomes was obtained following the full process of literature based validation techniques. The clinical and therapeutic benefit of this novel topical formulation was carried out on 36 patients with mild to moderate plaque psoriasis in a double-blind, placebo-controlled clinical trial. The quality of Life (QOL) questionnaire and PASI (psoriasis area & severity index) scores as well as photos before and after treatment were used to evaluate the outcome. The reported side effects were also recorded and were trivial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304203106N13**

Registration date: **2013-06-11, 1392/03/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

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

Expected recruitment start date

2012-04-06, 1391/01/18

Expected recruitment end date

2012-12-15, 1391/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double blind, placebo controlled study of standardized hydro-alcoholic extract of *Curcuma longa* on plaque psoriasis

Public title

Study of standardized hydro-alcoholic extract of *Curcuma longa* on plaque psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients diagnosed with plaque Psoriasis, both sexes (male and female) with the age group of 18-70 years old; stable patients with discontinued topical treatment for 2 weeks or 2 month for systemic treatments prior to the study. Exclusion criteria: pregnancy; lactation; patients with severe skin infections or any malignancies; history of allergies to the active ingredient of the product.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **36**

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**

Islamic Azad University, Pharmaceutical Sciences
Branch

Street address

No1, Yakhchal street, Dr. Shariati Avenue

City

Tehran

Postal code

1941933111

Approval date

2011-05-02, 1390/02/12

Ethics committee reference number

13993

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

psoriasis

ICD-10 code

L40.0

ICD-10 code description

Psoriasis vulgaris

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

Redness

Timepoint

Week 0 (baseline), week 3,6,9 to complete the follow-up

Method of measurement

1.Psoriasis questionnaire2.Psoriasis quality of life questionnaire3. photography: before, during &after treatment4. PASI calculator

2**Description**

Thickness

Timepoint

Week 0 (baseline), week 3,6,9 to complete the follow-up

Method of measurement

1.Psoriasis questionnaire2.Psoriasis quality of life questionnaire3. photography: before, during &after treatment4. PASI calculator

3**Description**

Scaling

Timepoint

Week 0 (baseline), week 3,6,9 to complete the follow-up

Method of measurement

1.Psoriasis questionnaire2.Psoriasis quality of life questionnaire3. photography: before, during &after treatment4. PASI calculator

4**Description**

Involved area

Timepoint

Week 0 (baseline), week 3,6,9 to complete the follow-up

Method of measurement

1.Psoriasis questionnaire2.Psoriasis quality of life questionnaire3. photography: before, during &after treatment4. PASI calculator

5**Description**

PASI score

Timepoint

Week 0 (baseline), week 3,6,9 to complete the follow-up

Method of measurement

1.Psoriasis questionnaire2.Psoriasis quality of life questionnaire3. photography: before, during &after treatment4. PASI calculator

Secondary outcomes

1

Description

Reported side effects (systemic and local)

Timepoint

Patients were given a telephone number to call during treatment. Patient could report any side effects 24/7 as well as during follow-ups, all the way through the treatment and after completion.

Method of measurement

Vigorous medical examination by the consultant dermatology in week 0,3,6,9 . Side effects Questionnaire, photography

Intervention groups

1

Description

Herbal microemulsion: patients were instructed to apply the Herbal microemulsion of 0.5% curcumin twice a day on plaque lesions.

Category

Treatment - Drugs

2

Description

Placebo: patients were instructed to apply the Placebo microemulsion twice daily on plaque lesions.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomainsi hospital

Full name of responsible person

Dr Parvin Mansouri

Street address

Skin clinic - Imam Khomeini hospital- Bagherkhan avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Self supported and Islamic azad university pharmaceutical branch

Full name of responsible person

Dr. Orkideh Ghorban dadras

Street address

No1. Yakhchal street, Dr. Shariati Avenue

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Self supported and Islamic azad university pharmaceutical 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University, Pharmaceutical Sciences Branch

Full name of responsible person

Dr. Mehdi Rajabi

Position

Assistant professor- clinical pharmacy expert

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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