Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

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 hyperprolifration 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

2013-06-11, 1392/03/21

Registrant information

Name
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Pharmaceutical Sciences Branch, Islamic Azad University (IAU)
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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 Khomaini 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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1941933111
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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