Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of alcoholic extract of Verbascum thapsus ointment on psoriasis

Protocol summary

Summary

Psoriasis, an autoimmune and recurrent chronic inflammatory skin disease that is influenced by both genetic and triggers factors. About 1-3% of the world wide 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 current agents. Based on several studies, verbascum thapsus can inhibit several inflammatory enzymes mainly involved in the inflammatory process of Psoriasis and it has immunomodulator effect. Therefore, we decided to target this well known herbal agent with fantastic safety profile to be formulated as a novel topical ointment 10%. Prior to the formulation, the hydro alcoholic extract of verbascum leaf was obtained following the full process of literature based validated technique. The clinical and therapeutic benefit of this novel topical formulation was carried out on 25 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) score as well as photos before and after treatment use to evaluate the outcome. The duration of study is at least two month.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404093106N16**
Registration date: **2014-05-12, 1393/02/22**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-05-12, 1393/02/22

Registrant information

Name
Farshad Hashemian

Name of organization / entity
Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

1- Islamic Azad University, Pharmaceutical Sciences Branch 2- investigators financial sources

Expected recruitment start date

2014-04-14, 1393/01/25

Expected recruitment end date

2014-06-15, 1393/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of alcoholic extract of Verbascum thapsus ointment on psoriasis

Public title

Investigation effect of Verbascum thapsus ointment on psoriasis patients

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients older than 18 years old; patients with low-to-severe plaque Psoriasis lesions are symmetric; no other underlying disease or are not pregnant; patients who do not receive treatment or previous treatment for at least two weeks before they are cut. Exclusion criteria: in case of dissatisfaction and sensitivity; patients who did not complete the treatment process and do not continue; pregnancy and lactation.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **25**
Randomization (investigator's opinion)
Not 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
No.99, Yakhchal street, Dr. Shariati Avenue
City
Tehran
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
58

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
1. Redness, thickness, scaling and involved area.2. PASI score(psoriasis area & severity index)
Timepoint
Week 0 (baseline), week 3,6,9 to complete the follow-up
Method of measurement
1. Psoriasis questionnaire/ 2. Psoriasis quality of life questionnaire/3. photography: before, during &after treatment/4. 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, Questionnaire, photography, scoring

Intervention groups

1

Description
Herbal ointment: containing 10 % Verbascum thapsus extract in plastibase. patients were instructed to apply the Herbal ointment twice a day.
Category
Treatment - Drugs

2

Description
placebo ointment: containing plastibase. patients were instructed to apply twice a day.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomaini hospital
Full name of responsible person

Dr Parvin Mansoori

Street address

Imam Khomeini Hospial complex, Keshavarz blv.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Pharmaceutical Sciences Branch

Full name of responsible person

Dr. Orkideh Ghorban dadras

Street address

No.99, Yakhchal street, Dr. Shariati Avenue Tehran

City

Tehran

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Pharmaceutical science branch of Islamic azad university

Full name of responsible person

Dr. Farshad Hashemian

Position

Assistant professor

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