

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of Sambucus ebulus topical preparation and placebo, on skin disorders in psoriasis patients, a clinical trial

Protocol summary

Summary

The aim of this clinical study is to compare the effect of Sambucus ebulus extract topical preparation and placebo, on psoriasis skin disorders. (This plant is native at the north of Iran and has been used in traditional medicine as analgesic and anti-inflammatory, and high anti-oxidant activity). The patients who are suffering from psoriasis are included in this study. Thirty patients in intervention group will receive Sambucus ebulus topical preparation and the 30 patients in the control group will receive placebo. Patients are randomly allocated to the intervention and control group. Randomization will be performed using random number table. The prescriber and evaluator will be blind during the study. The study will be done in one center. All of the patients with psoriasis skin disorder (men or women) will be included in this study and every one with sensitivity to topical preparation will be excluded. The patients will receive topical preparation (Sambucus ebulus topical preparation or placebo) twice a day for two months and the pruritus severity index and other symptoms such as dryness and ulceration due to scratching will be recorded.

General information

Acronym

Effect of Palem on psoriasis

IRCT registration information

IRCT registration number: **IRCT2017072210203N8**

Registration date: **2017-07-24, 1396/05/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-24, 1396/05/02

Registrant information

Name

Majid Saeedi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1354 3082

Email address

msaeedi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sambucus ebulus topical preparation and placebo, on skin disorders in psoriasis patients, a clinical trial

Public title

Evaluation of Palem topical preparation on psoriasis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with psoriasis during 3 months, at the age of 13 years and more; 3 times pruritus during last two weeks before study; or receive

treatment during one month without any significant response. Exclusion criteria: pregnancy and breast feeding; sensitivity to topical preparation.

Age

From **13 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Every patient allocates one code based on random number table, and receives drug or placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Moallem square

City

Sari

Postal code

Approval date

2017-02-28, 1395/12/10

Ethics committee reference number

IR.MAZUMS.REC.95.2599

Health conditions studied

1

Description of health condition studied

Psoriasis

ICD-10 code

L40.1

ICD-10 code description

Generalized pustular psoriasis

Primary outcomes

1

Description

PASI Score

Timepoint

Time zero and after 4 and 8 weeks

Method of measurement

Based on area (head, trunk, arms, legs) and erythema, induration and scaling by physical examination.

Secondary outcomes

1

Description

Pruritus

Timepoint

time zero, and after 4 and 8 weeks

Method of measurement

qualitative questioner (0 to 4)

Intervention groups

1

Description

Intervention group: Sambucus ebulus topical preparation 2% (ointment) formulated in Sari's faculty of pharmacy, two times a day for two months

Category

Treatment - Drugs

2

Description

Control group: Placebo (ointment without extract), two times a day for two months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Boo Ali hospital

Full name of responsible person

Majid Saeedi

Street address

Pasdaran Blvd.

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Prof. Ahmad Ali Enayati

Street address

Moallem square

City

Sari

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Position

Pharmaceutics, Professor

Other areas of specialty/work**Street address**

18th. km of Khazar road

City

Sari

Postal code**Phone**

+98 11 3354 3082

Fax**Email**

majsaeedi@gmail.com

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

Mazandaran University of Medical Sciences

Full name of responsible person

Majid saeedi

Position

Pharmaceutics, Professor

Other areas of specialty/work**Street address**

18th. km of Khazar road

City

Sari

Postal code**Phone**

+98 11 3354 3082

Fax**Email**

majsaeedi@gmail.com

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

Mazandaran University of Medical Sciences

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18th. km of Khazar road

City

Sari

Postal code**Phone**

+98 11 3354 3082

Fax**Email**

majsaeedi@gmail.com

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