

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of Dorema ammoniacum topical ointment on mild to moderate plaque psoriasis

Protocol summary

Study aim

Investigating the therapeutic effect of Dorema ammoniacum ointment on improving psoriasis skin lesions

Design

clinical trial ; three blind study ; phase 3 The sample size was calculated by using the PASS software and for the test of the difference between the average pass score of two independent groups and considering the power of 90% and the confidence of 95% and the standard deviation of 3 and the effect size of 2.5 units in each group of 32 people, which considering It was determined that 3 people drop out in each group of 35 people.

Settings and conduct

Patients with psoriasis referred to Imam Reza Hospital in Mashhad, which has inclusion criteria, are assigned to intervention and control groups and receive Dorema ammoniacum ointment or placebo for four weeks. Clinical symptoms will be evaluated based on the PASI score at the beginning and end of the study. Patients, outcome evaluator and data analyst will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 12 years and older, Suffering from chronic plaque-type psoriasis, The extent of infection is less than 10% of the body's surface Exclusion criteria: Having serious liver or kidney diseases, Using topical medicine in the last 14 days and systemic medicine in the last 30 days, Pregnancy or planning to become pregnant, breastfeeding, History of allergy to herbal medicines, Abnormal laboratory findings, Taking local or systemic medications that have a positive or negative effect on the course of the disease.

Intervention groups

intervention , the test group consisted of ointment containing 15% ash, 10% vinegar, 20% wheat oil and 55% oserin. In the control group, topical ointment with the same color, smell and consistency as the original ointment is used.

Main outcome variables

Measurement of extent ' inflammation and scaling of the lesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220616055195N1**

Registration date: **2023-03-13, 1401/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-13, 1401/12/22**

Update count: **0**

Registration date

2023-03-13, 1401/12/22

Registrant information

Name

Zahra Naseri por yazdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3551 0354

Email address

naseripz981@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-05, 1401/12/14

Expected recruitment end date

2023-09-05, 1402/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Dorema ammoniacum topical ointment on mild to moderate plaque psoriasis

Public title

Effect of Dorema ammoniacum ointment on psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic plaque form psoriasis patients Plaque size : lower than 10 % Age : older than 12 years old

Exclusion criteria:

Taking topical medicine in the last 14 days and systemic drug in the 30 last days Pregnancy or planning to be pregnant or breast feeding History of allergy to herbal medicines Presence of abnormal laboratory finding Taking local or systemic medicine that has a positive or negative effect on the course of the disease Having serious liver or kidney disease

Age

From **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Block method Allocation Concealment : closed and sealed envelopes triple blinded : people under study assessors analytic in the placebo group the patient is unaware of the type of ointment . instead of intervention and control group A and B are used to blind the analyst . the evaluation of the outcome is done by a person outside the research group .

Blinding (investigator's opinion)

Triple blinded

Blinding description

In the placebo group the patient is unaware of the type of ointment . instead of intervention and control group A and B are used to blind the analyst . the evaluation of the outcome is done by a person outside the research group .

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

School of medicine, Kalantari Blvd, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2022-11-19, 1401/08/28

Ethics committee reference number

IR.MUMS.REC.1401.312

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

chronic plaque psoriasis

ICD-10 code

L40.0

ICD-10 code description

Psoriasis vulgaris

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

Plaque-type psoriasis patients with lesion involvement less than 10%

Timepoint

before the start of the intervention, day 14, day 28, day 42 and day 56 after the start of the intervention

Method of measurement

PASI questionnaire and DLQI questionnaire

Secondary outcomes**1****Description**

Investigating the quality of life based on the DLQI questionnaire

Timepoint

Before the intervention, week 2, week 4, week 6, week 8 after the intervention

Method of measurement

Dermatology Questionnaire for Quality of Life (DLQI)

Intervention groups

1

Description

Intervention group: The ointment contains D0orema ammoniacum and OSERIN which is used on the lesion twice a day for two months. The ointments are formulated and provided by a pharmacist at the pharmaceutical laboratory of the school of Persian and complementary medicine at Mashhad University of Medical Sciences.

Category

Treatment - Drugs

2

Description

Control group: In the control group, topical ointment with the same color, smell, and consistency as the original ointment is used on the lesion twice a day for two months. The ointments are formulated and provided by a pharmacist at the pharmaceutical laboratory of the school of Persian and complementary medicine at Mashhad University of Medical Sciences.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Zahra Naseriporyazdi

Street address

Emam Reza Hospital, Dr.Shariati Square

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Naseripz981@mums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour-Mobarhan

Street address

Deputy of Research and Technology, Gharshi

Building, Daneshgah St., Mashhad, Iran.

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Email

vcresraech@mums.ac.ir

Web page address

<https://v-research.mums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Naseriporyazdi

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

Others

Street address

No. 60, Imam Reza 10, Vilashahr

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09117507723

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Alireza Derakhshan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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University campus, Azadi Square

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Personal data of study participants can be shared after de-identification.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions and people working in the industry.

Under which criteria data/document could be used

Approved for use in the treatment of patients with plaque psoriasis Allowed for other statistical analyses

From where data/document is obtainable

From Zahra Naseripour Yazdi with email address:
Naseripz981@mums.ac.ir Phone number:
009809157101309

What processes are involved for a request to access data/document

After mentioning the name and organization of the user and explaining the type of use of the information in the email address The specifications will be checked and will be made available after one month.

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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Naseriporyazdi

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No. 60, 10 Mam Reza St., Vilashahr

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