Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 assesors analystic 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
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 915 710 1309
Email
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.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3881 4043
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
City
Mashhad
Province
Razavi Khorasan
Postal code
09117507723
Phone
+98 915 710 1309
Email
Naseripz981@mums.ac.ir

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
Street address
School of Persian and Complementary Medicine, University campus, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3841 2081
Email
derakhshanAR@mums.ac.ir

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
City
Mashhad
Province
Razavi Khorasan
Postal code
09117507723
Phone
+98 915 710 1309
Email
Ńaseripz981@mums.ac.ir

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