Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the effectiveness of topical formulation of Boswellia serrata extract compared to clobetasol in the treatment of psoriasis vulgaris; a randomized controlled clinical trial

Protocol summary

Study aim

Evaluation of the effectiveness of topical formulation of Boswellia serrata extract compared to clobetasol in the treatment of psoriasis vulgaris

Design

Two arm parallel groups randomized trial with the control group

Settings and conduct

The study will be performed in Sedigheh Tahereh Research Center of Isfahan. Patients with inclusion criteria will be randomly assigned to drug or control groups. The sample size is 22 patients. For patients in the drug group, a 10% boswellia Ointment will be applied for four weeks, while for patients of the control group, 0.05% clobetasol Ointment will be used for four weeks. Before and at the end of the intervention, the size of lesions according to BSA percentage and Psoriasis Area and Severity Index (PASI) score will be recorded for each Patient. Finally, the mentioned variables will be compared between the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mild psoriasis vulgaris in the areas of limbs and trunk; Mild psoriasis is defined as Involvement of a maximum of 10% of the body surface area (BSA)./ Exclusion criteria: 1-Incidence of other types of psoriasis (erythrodermic, guttate, ...) 2-Incidence of Facial or scalp psoriasis 3-Incidence of psoriatic arthritis 4-Receiving systemic anti-psoriasis treatment and phototherapy during last month 5-Receiving topical anti-psoriasis treatment during last two weeks 6-Autoimmune disorders 7-Incidence of other chronic skin disorders (pemphigus, eczema, dermatitis, lichen planus) 8-Infection in the lesion 9-Pregnancy 10-Lactation

Intervention groups

Intervention group: 10% boswellia Ointment, for 28 days Control group: 0.05% clobetasol Ointment, for 28 days

Main outcome variables

1- Change in the size of lesions according to BSA percentage Change at the end of the intervention 2- Change in the Severity of lesions according to PASI Change at the end of the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023282N23**
Registration date: **2022-09-13, 1401/06/22**
Registration timing: **prospective**

Last update: **2022-09-13, 1401/06/22**
Update count: **0**

Registration date

2022-09-13, 1401/06/22

Registrant information

Name

Rasool Soltani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-21, 1401/09/30

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of topical formulation of Boswellia serrata extract compared to clobetasol in the treatment of psoriasis vulgaris; a randomized controlled clinical trial

Public title
Evaluation of the effectiveness of Boswellia serrata in the treatment of psoriasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Mild psoriasis vulgaris in the areas of limbs and trunk; Mild psoriasis is defined as Involvement of a maximum of 10% of the body surface area (BSA).
Exclusion criteria:
Incidence of other types of psoriasis (erythrodermic, guttate, ...) Incidence of Facial or scalp psoriasis Incidence of psoriatic arthritis Receiving systemic anti-psoriasis treatment and phototherapy during last month Receiving topical anti-psoriasis treatment during last two weeks Autoimmune disorders Incidence of other chronic skin disorders (pemphigus, eczema, dermatitis, lichen planus) Infection in the lesion Pregnancy Lactation
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
All the arrangements of the two groups will be drawn in pairs in quadruple blocks and each block will be numbered from 1 to the end. Using a table of random numbers, the blocks are selected in order and based on the arrangement of that block, patients will be divided into one of two groups according to the order of admission.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar-Jerib Avenue, Vice-chancellery for research, Isfahan University of Medical Sciences, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2022-08-23, 1401/06/01
Ethics committee reference number
IR.MUI.MED.REC.1401.205

Health conditions studied

1

Description of health condition studied
Psoriasis vulgaris
ICD-10 code
L40.0
ICD-10 code description
Psoriasis vulgaris

Primary outcomes

1

Description
change in Psoriasis Area and Severity Index (PASI) Before the intervention and at the end of the intervention
Timepoint
Before the intervention, 28 days after the start of intervention
Method of measurement
The online calculator that is available on the following website:
https://www.mdcalc.com/calc/10182/psoriasis-area-severity-index-pasi

2

Description
Percentage change in body surface area (BSA) at the end of the intervention
Timepoint
Before the intervention, 28 days after the start of intervention
Method of measurement

chart

Secondary outcomes

1

Description
Intensity of itching
Timepoint
Before the intervention, 28 days after the start of intervention
Method of measurement
Use Visual Analogue Scale (VAS) from 0 (No itchy) to 10 (Extremely itchy) by patients

2

Description
Proportion of people with PASI 50 (decrease of at least 50% in the PASI score) at the end of the intervention
Timepoint
Before the intervention, 28 days after the start of intervention
Method of measurement
Observation

3

Description
Proportion of people with complete recovery (PASI 90) at the end of the intervention
Timepoint
Before the intervention, 28 days after the start of intervention
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: 10% boswellia Ointment, made by Isfahan University of Medical Science, School of Pharmacy,twice a day, for 28 days
Category
Treatment - Drugs

2

Description
Control group: 0.05% clobetasol Ointment,twice a day, for 28 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Dermatology and Leishmaniasis Research Center Clinic
Full name of responsible person
Rasool Soltani
Street address
Khorram Ave. Skin and Leishmaniasis Research Center
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isfahan
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Isfehan
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8187698191
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sdlrc@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo Javanmard
Street address
Hezar-Jerib Ave.
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7346181746
Phone
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Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person
Rasool Soltani

Position
Associated Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no necessity.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available