

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

Isfahan

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

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Khorram Ave. Skin and Leishmaniasis Research Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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
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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