Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of a topical Boswellia-based cream (Persian Medicine product) on skin manifestations and quality of life in mild to moderate plaque psoriasis

Protocol summary

Study aim
The effect of a topical Boswellia carterii-based cream (Persian Medicine product) on the skin manifestation in mild to moderate plaque psoriasis

Design
Randomized clinical trial of 108 patients in intervention and control groups, parallel groups, double blind.

Settings and conduct
Individuals are randomly divided into two groups of intervention and placebo and treated with topical cream for one month at the clinic of Center for Research and Training in Skin Diseases And Leprosy in Tehran. The physician and patients are blind.

Participants/Inclusion and exclusion criteria
Inclusion: 1. 18-70 years 2. Diagnosed with clinical of mild to moderate plaque psoriasis; 3. PASI score <12 4. Involvement of body surface area< 10%; 5. Patients who provide written informed consent; Exclusion: 1. Pregnant or breast-feeding females; 2. Known allergic reactions to components of the study medication; 3.Quttate, erythrodernic, or pustular psoriasis at the time of screening or patients with psoriasis vulgaris with face involvement only; 4.Use of drugs that aggravate psoriasis such as beta-blockers, anti malaria, terbinafine, calcium channel blockers, interleukin and lithium; 5. Previous treatment with biologic or immunosuppressive drugs, systemic corticosteroids and ultraviolet B phototherapy after taking psoralen within the previous four weeks; 6.Previous treatment with topical corticosteroids within the previous two weeks; 7. Severe psoriasis; 8. Patients who require systemically acting medications; 9. Presence of an infectious ulcer or cancer in the treatment area;

Intervention groups
Intervention group uses 1 gr of topical cream on the skin lesion twice daily for a 4-week (28 days). The control group also uses the same cream in the same dose.

Main outcome variables
PASI score (psoriasis area and severity index) , PGA score (physician global assessment)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180804040694N1**
Registration date: **2018-12-31, 1397/10/10**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-31, 1397/10/10**
Update count: **0**

Registration date
2018-12-31, 1397/10/10

Registrant information

Name
Fateme Fadaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2234 6099

Email address
f-fadaei@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-06-22, 1398/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of a topical Boswellia-based cream (Persian Medicine product) on skin manifestations and quality of life in mild to moderate plaque psoriasis

Public title
"Effect of Boswellia in psoriasis"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosed with clinical of mild to moderate Plaque Psoriasis Age between 18-70 years old PASI score <12 Involvement of body surface area <10% Written informed consent
Exclusion criteria:
Gguttate, erythrodernic, psoriatic arthritis or pustular psoriasis at the time of screening; psoriasis vulgaris patients with face involvement only; Known allergic or hypersensitive reactions to cream components; Using medications that could trigger psoriasis like beta blockers, antimalarials, terbinafine, calcium channel blockers, interleukins and lithium; Previous treatment with systemic corticosteroids, biologic and immunosuppression drugs or psoralen ultraviolet A therapy within the previous four weeks; Previous treatment with local corticosteroids within the previous two weeks; Presence of skin infections or malignancy in the treatment area; Severe psoriasis; Patients who require systemically acting medications for the treatment of psoriasis; Pregnant or breast-feeding females;
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, randomly permuted blocks of size 6 are used to assign participants into two groups (treatment and placebo groups). There are 108 participants in this study and as a result, 18 blocks of size 6 is considered. With blocks of size six, for example the order in which the integers 1,2,3,4, 5, 6 appear in a random permutation determines which patients receive the treatment (those whose numbers appear first, second and third) and which receive the placebo (those whose numbers appear fourth, fifth and sixth). For example, if numbers appear in the order of 4, 1, 6, 3, 2 and 5, the assignment of participants to the study groups will be as follows: Placebo, Treatment, Placebo, Treatment, Treatment, and Placebo. This procedure will be performed to obtain all 18 blocks of size six (1). Fleiss JL. Design and analysis of clinical experiments: John Wiley & Sons; 2011.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participant, physician, clinical care, researcher and outcomes evaluation are blind in this study .According to the drug and placebo are similar in appearance, color, weight, smell, and manner of use.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Science
Street address
13th Floor, Block A, Headquarters of Ministry of Health and Medical Education, Sima-ye Iran St.,Farahzadi Blvd., Qods Town
City
Tehran
Province
Tehran
Postal code
1981843631
Approval date
2018-10-29, 1397/08/07
Ethics committee reference number
IR.TUMS.VCR.REC.1397.523

Health conditions studied

1

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

Primary outcomes

1

Description
The Psoriasis Area Severity Index (PASI);
Timepoint
PASI score is evaluated at baseline, day 14 and day 28;
Method of measurement
Fotofinder device;

Secondary outcomes

1

Description
Physician Global Assessment (PGA score);
Timepoint
Outcoms are evaluated at baseline, day 14 and day 28;
Method of measurement
Physician's observation;

2

Description
The body surface area (BSA);
Timepoint
Outcoms are evaluated at baseline, day 14 and day 28;
Method of measurement
Palm method (patient's handprint);

3

Description
Assess pruritus intensity;
Timepoint
Outcoms are evaluated at baseline, day 14 and day 28;
Method of measurement
The VAS (visual analoge scale) is used. It is a criterion 10 grades are used and the patient shows the quality in quantitative form with the number;

4

Description
The DLQI (dermatology life and quality index) of the psoriasis patients;
Timepoint
Outcoms are evaluated at baseline, day 14 and day 28;
Method of measurement
Questionnaire;

5

Description
Photo of Plaque Psoriasis
Timepoint
Outcoms are evaluated at baseline, day 14 and day 28;
Method of measurement
Camera;

6

Description
Patient's satisfaction;
Timepoint
Outcoms are evaluated at day 14 and day 28;
Method of measurement
The VAS (visual analoge scale) is used. It is a criterion 10 grades are used and the patient shows the quality in quantitative form with the number;

7

Description
Adverse events of the drug;
Timepoint
Outcoms are evaluated at day 14 and day 28;
Method of measurement
Questionnaire;

Intervention groups

1

Description
Intervention group: The patients use 1gr of topical Frankincense based cream on the skin lesion twice a day for a period of four weeks (28 days). Measure of topical medication is Finger Tip Unit (FTU)
Category
Treatment - Drugs

2

Description
Control group: The patients consumed 1 gr of the same cream in consistency, odor, and color without combining Frankincense on the skin lesion twice a day for a four-week period (28 days).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University of Medical Sciences - School of Persian Medicine is funding the run-in costs for t
Full name of responsible person
Fateme Fadaei
Street address
No.79, Naderi St., Taleqani St., Enghelab Sq.
City
Tehran
Province
Tehran
Postal code
1416613675
Phone
+98 21 8897 2220
Email

support@dframeworks.com

Web page address

http://crtsdl.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Hossein Ayati

Street address

No. 27, North Sarparast St., Felestin Squ.

City

Tehran

Province

Tehran

Postal code

1415663361

Phone

+98 21 8897 6529

Fax

+98 21 8897 6529

Email

mh-ayati@tums.ac.ir

Web page address

http://stpm.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

50

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

Tehran University of Medical Sciences

Full name of responsible person

Fateme Fadaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No. 20, 4h Laleh St., Shaghayegh Blvd., Saadat Abad

City

Tehran

Province

Tehran

Postal code

19818443631

Phone

+98 21 2234 6099

Fax

+98 21 2234 6099

Email

f-fadaei@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fateme Fadaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No. 20, 4th Laleh St., Shaghayegh Blvd., Saadat Abad

City

Tehran

Province

Tehran

Postal code

1981843631

Phone

+98 21 2234 6099

Fax

+98 21 2234 6099

Email

f-fadaei@razi.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fateme Fadaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No.20,4th st,Shaghayegh Blvd,Behrood Square,Sa'adat Abad

City

Tehran

Province

Tehran

Postal code

1981843631

Phone

+98 21 2234 6099

Fax

+98 21 2234 6099

Email

f-fadaei@razi.tums.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

Skin lesions and quality of life database will be share in patients with mild to moderate psoriasis.

When the data will become available and for how long

" The results will be available 6 months after printing"

To whom data/document is available

Researchers working in academic and scientific institutions and those involved in the pharmaceutical industry.

Under which criteria data/document could be used

They make the low risk drug.

From where data/document is obtainable

Fateme Fadaei , The University of Tehran, Ahmadiyyeh Persian Medicine Clinic. f-fadaei@razi.tums.ac.ir

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

First, they will send an application to Mrs. Dr. Shirbeigi, then they will have access to the documentations after review for 6 months, if agreed necessary. l.shirbeigi@yahoo.com

Comments