

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Efficacy of flax seed oil in treating mild to moderate psoriasis vulgaris comparing with topical Bethamethasone: A randomized, double-blind, clinical trial

Protocol summary

Study aim

Evaluation of the effect of flaxseed on the treatment of skin lesions with mild to moderate severity of psoriasis vulgaris compared with topical betamethasone ointment.

Design

A double-blind randomized clinical trial on 50 patients

Settings and conduct

- Among the clients of the dermatological clinic for Tehran Hazrat-e-Rasool Akram Hospital, 50 patients with psoriasis vulgaris, having the survey inclusion criteria, will be selected (by a plan executor physician) and included in the survey, giving some verbal comments to them and taking their written consent forms. At the beginning of the study, a questionnaire for individual information, and also two PASE and life quality questionnaires will be filled out by the researcher, observing the lesions and inquiring the patient. Then, the patients will be divided into two groups randomly, based on the table of random numbers; one group will apply Betamethasone product, and the second group will apply flax seed oil ointment on the lesions locally twice a day for 4 weeks. At the end of 4th week, the patients will be evaluated again by the therapist and researcher, based on both questionnaires, observing the lesions, and also the questions of the questionnaires. Moreover, both groups will be inquired about their satisfaction with treatment, according to scoring

Participants/Inclusion and exclusion criteria

- All patients between 18-60 years old, suffering psoriasis vulgaris plaque type with mild to moderate signs, not with intensifying psoriasis disease, and not to take medicines affecting psoriasis

Intervention groups

- In the control group, Betamethasone ointment is applied twice a day, and in the intervention group, the ointment of flax seed oil is applied locally twice a day for 4 weeks..

Main outcome variables

Redness, Degree of Thickness, Degree of Scaling, Extent of Scrap, Quality of Life, Passive Intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191211045692N1**

Registration date: **2020-04-01, 1399/01/13**

Registration timing: **retrospective**

Last update: **2020-04-01, 1399/01/13**

Update count: **0**

Registration date

2020-04-01, 1399/01/13

Registrant information

Name

farshad mohammadian rasanan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8837 6260

Email address

mohammadian.fa@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-09, 1398/11/20

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of flax seed oil in treating mild to moderate psoriasis vulgaris comparing with topical Bethamethasone: A randomized, double-blind, clinical trial

Public title

Efficacy of flax seed oil in treating mild to moderate psoriasis vulgaris comparing with topical Bethamethasone

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Type of psoriasis vulgaris disease with mild to moderate plaque type - Not to suffer underlying diseases disrupting the therapy, such as obesity, pregnancy, dialysis, AIDS, psychotic disorder, thyroid and parathyroid T d iseases
Not to use medicines affecting psoriasis disease, such as Beta-blocker, lithium, anti-malaria, corticosteroids and systemic steroids, calcium channel blockers, interleukin
Confirmation of clinical diagnosis by a dermatologist

Exclusion criteria:

- Suffering each of the abovementioned diseases or confirming the diagnosis of any disease, interfering with the treatment, and mentioned in the inclusion criteria, in any moment of the treatment cycle - Patient dissatisfaction with going on the treatment Any physical and chemical trauma and surgery, which inevitably makes the patient involved, and leads to the disease exacerbation

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

A random number is allotted the patients, through the table of random numbers; a sealed envelope is delivered to him, and a random code is allocated to his medicine box. Data analysis is performed by the statistical software.

Blinding (investigator's opinion)

Double blinded

Blinding description

- The participants will receive a code, based on the table of random numbers; then, according to the code, they will receive one of the containers containing the product

or Betamethasone. Both medicines are in the same containers with a uniform shape and color, and the patient will receive a treatment container and medicine, merely based on the code, inserted on the treatment box. This code will be repeated by the end of the study, neither the clinical observer nor the patient will be aware of the received medicine type, and only the container code will be given to them.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of Iran University of Medical Sciences

Street address

Iran University of Medical Science , Hemmat BLV

City

تهران

Province

Tehran

Postal code

1449614535

Approval date

2018-08-11, 1397/05/20

Ethics committee reference number

IR.IUMS.REC.1398.466

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

PSORIASIS VULGARIS PLAQUE TYPE

ICD-10 code

L40.0

ICD-10 code description

Psoriasis vulgaris

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

Erythem

Timepoint

At First and End of One Month

Method of measurement

PASI QUESTIONARE

2

Description

Scaling

Timepoint

At First and End of One Month

Method of measurement

PASI QUESTIONARE

3

Description

Induration

Timepoint

At First and End of One Month

Method of measurement

PASI QUESTIONARE

4

Description

Area

Timepoint

At First and End of One Month

Method of measurement

PASI QUESTIONARE

5

Description

PASI Score

Timepoint

At First and End of One Month

Method of measurement

PASI QUESTIONARE

6

Description

QUALITY OF LIFE

Timepoint

FIRST AND ONE MONTH LATER

Method of measurement

DLQ QUESTIONARE

7

Description

SATICFACTION

Timepoint

FIRST AND ONE MONTH LATER

Method of measurement

SATISFACTION QUESTION

Secondary outcomes

empty

Intervention groups

1

Description

- Intervention group: in this group, the certified flax seed

oil, produced by Barij Essence Co., will be applied in the form of an ointment, delivered to the patient in the containers with a uniform appearance, applied on the lesions twice a day, and given a massage. The patient will apply the ointment from the beginning of the study, be reevaluated by a physician, and the related questionnaires will be filled out at the end of the first month. To avoid any disruption in the observation and evaluation processes to fill the questionnaires, the primary and final patient's evaluations will be performed by the same personnaires will be completed.

Category

Treatment - Drugs

2

Description

- Control group: in this group, Betamethasone ointment will be applied in the same container; the patients will be examined at the beginning of the study and the end of the first month by a physician, based on the questionnaires. Betamethasone ointment will be given to the patients in the same and uniform containers; it must be applied on lesions twice a day, and given massages. n the lesions and massaged.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram General hospital

Full name of responsible person

Farshad Mohammadian

Street address

Niyayesh St, Sattar khan, Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5001

Email

PR@iums.ac.ir

Web page address

<http://hrmc.iums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Farshad Mohammadian Rasanan

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2030

Email

ivco@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Farshad Mohammadian Rasanan

Position

Consultant

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No .42, Dadman blv, Shahrake Gharb, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1467764513

Phone

+98 21 8837 6260

Email

fmr4077@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Farshad Mohammadian Rasanan

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No.42, Dadman Blv, Shahrake Garb

City

Tehran

Province

Tehran

Postal code

1467764513

Phone

+98 21 8837 6260

Fax

Email

mohammadian.fa@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Farshad Mohammadian Rasanan

Position

Consultant

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No.42, Dadman Blv, Shahrake Gharb

City

Tehran

Province

Tehran

Postal code

1467764513

Phone

+98 21 8837 6260

Email

fmr4077@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available