Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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 Bethamethasonel
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 Commitees of Iran University f 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 QUESTIONNARE

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran 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
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

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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