Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The impact of Florabile syrup on intensity (inflammation, plaque, and scaling) of Psoriasis rashes in patients aged 20 to 50 years.

Protocol summary

Study aim

Determination of the impacts of of Florabile syrup on the severity of Psoriasis rashes in patients between 20 to 50 years. Determination and comparison of the frequency of; Psoriasis rashes erythema, Psoriasis rashes plaque, Psoriasis rashes scaling and the frequency of BSA (Body Surface Area); surface of the patient's body that is involved by Psoriasis rashs, before and after the intervention. Determination and comparison of the average of PASI (Psoriasiss Area and Severity Index) of patients before and after the intervention.

Design

Clinical experiment of pre and post (self-control), single group and not blind.

Settings and conduct

Patients with Psoriasis who visited doctor in Iranian medical clinics at Al-zahra, Amin, and Kashani hospitals in Isfahan consumed Florabile syrup three spoons diluted with a glass of water one hour before lunch for a 30 days period; and also it was suggested to the patients that they are supposed to report any adverse side effects.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20 to 50 years old patients with mild to moderate Psoriasis and patients whose bodies were involved below than 20 percent were participated in this study who did not take any medicine to treat psoriasis last three months. Exclusion criteria: Patients with diagnosis of generalized, unstable or pustular Psoriasis who had only skull, nail, flexor surfaces or palms and soles involvement, and patients who were pregnant or breastfeeding, and also patients who were allergic to Plum, Jujube, and Tamarindus indica-derived products were not included in this study.

Intervention groups

Consumer (group) of Florabile syrup

Main outcome variables

The frequency of erythema, plaque, scaling and BSA (Body Surface Area) decreases before and after intervention in patients; The average of PASI (Psoriasiss Area and Severity Index) decreases before and after intervention in patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408047000N1**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **retrospective**

Last update: **2020-05-04, 1399/02/15**
Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

Ameneh Parastegari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-16, 1397/12/25

Expected recruitment end date

2019-10-30, 1398/08/08

Actual recruitment start date

2019-03-16, 1397/12/25

Actual recruitment end date

2020-03-03, 1398/12/13

Trial completion date
2020-03-18, 1398/12/28

Scientific title
The impact of Florabile syrup on intensity (inflammation, plaque, and scaling) of Psoriasis rashes in patients aged 20 to 50 years.

Public title
The impact of Florabile syrup on intensity of Psoriasis rashes.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patient must be between 20 to 50 years old. Patients should have mild to moderate Psoriasis and their body should be involved less than 20%. If patient has taken any other drugs to treat Psoriasis, he or she should not consume new dug for three months.

Exclusion criteria:
Patients with generalized, unstable, or pustular Psoriasis who have only skull, nails, flexor surfaces or palms and soles involvement. Patients who are pregnant or breastfeeding. Patients who are allergic to plums, jujube, and Tamarindus indica-derived products.

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **25**
Actual sample size reached: **25**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
This is a semiexperimental pre and post control study (self-control) which is going to be dine on patients with Psoriasis. The drug under study is available in market and is effective on liver disease treatments; this survey is to study the impact of this syrup on psoriasis. This is a kind of herbal medicine with no known side effects.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezarjerib Street.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2019-03-13, 1397/12/22

Ethics committee reference number
IR.MUI.MED.REC.1397.344

Health conditions studied

1

Description of health condition studied
Psoriasis

ICD-10 code
L40

ICD-10 code description
Psoriasis

Primary outcomes

1

Description
Suitable (PASI; Psoriasis Area Severity Index) for any patient.

Timepoint
At the beginning of the study (Before intervention) and after finishing the study.

Method of measurement
The software of calculating Psoriasis Severity Area Index. Version 1.7.2

2

Description
Percent of patients body surface involved (BSA; Body Surface Area).

Timepoint
At the beginning of the study (Before intervention) and after finishing the study.

Method of measurement
Calculating formula of the Percent of patients body surface involved.

3

Description
Erythema (redness) of Psoriasis rashes

Timepoint
At the beginning of the study (Before intervention) and

after finishing the study.

Method of measurement

Observation.

4

Description

Induration (plaque) of Psoriasis rashes.

Timepoint

At the beginning of the study (Before intervention) and after finishing the study.

Method of measurement

Observation.

5

Description

Desquamation (scaling) of Psoriasis rashes.

Timepoint

At the beginning of the study (Before intervention) and after finishing the study.

Method of measurement

Observation.

Secondary outcomes

empty

Intervention groups

1

Description

Experimental group: Consumer of Florabil syrup consisting:Tamarindus indica, Prune's domestica, Prune's spinosa L, Ziziphus juijub mill, Cordia myxa, Prunus armeniaca, Manna; and the benefits of this syrup includes increasing bile flow and facilitate it to exit the body, cleansing and strengthening the liver, controlling liver heat, removing tongue and skin dryness. No specific side effects have been reported for this medicine. 25patients aged 20 to 50 years with mild to moderate Psoriasis participated the study for a 30 day experimental period; and they diluted Florabile Syrup from Farateb company of Yazd containing three spoons (each spoon with an approximate volume of 15cc) with a glass of water and consumed one hour before lunch daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Persian Medicine Group Center, Amin hospital

Full name of responsible person

Mohammad Mazaheri

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2

Recruitment center

Name of recruitment center

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

No

Title of funding source
Isfahan 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
Ameneh Parastegari
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Graduated in general physician
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
Parts of data(Information about the consequences) allowed to be shared after making participants unknowable.
When the data will become available and for how long
Access time starts 6 months after printing the results.
To whom data/document is available
Dermatologists and complementary medicine specialist,

researchers employed in academic and scientific institutions.

Under which criteria data/document could be used

Only to help patients and for research purposes, any usage with citation.

From where data/document is obtainable

Visiting Iranian Medicine Center at Amin hospital in Isfahan or email to : mahdavi88311388@gmail.com

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

Email to mahdavi88311388@gmil.com and after sending the email, the data will be sent as soon as possible.

Comments