

# 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 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 rashes, before and after the intervention. Determination and comparison of the average of PASI (Psoriasis 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 (Psoriasis

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)

##### Phone

+98 31 3324 3522

##### Email address

mahdavi88311388@gmail.com

##### 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 drug 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 done 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**

Isfahan

**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 jujub 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

##### **Street address**

Persian Medicine Group Center, Amin hospital, Ibn

Sina Street.

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

8148653141

#### **Phone**

+98 31 3447 4246

#### **Email**

Mazaherimohammad@med.mui.ac.ir

### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Skin Diseases and Leishmaniasis Research Center

##### **Full name of responsible person**

Ameneh Parastegari

##### **Street address**

Skin Diseases and Leishmaniasis Research Center, Sedigheh Tahereh hospital, Khorram Street.

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8148653141

##### **Phone**

+98 31 3337 3736

##### **Email**

sdlrc@mui.ac.ir

##### **Web page address**

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Shaghayegh Haghjoy javanmard

##### **Street address**

Research and Technology Branch of University, Building No. 4, Isfahan University of Medical Sciences, Hezarjerib Street.

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

7346181746

##### **Phone**

+98 31 3668 5149

##### **Email**

research@mui.ac.ir

#### **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

**Position**

Graduated in general physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No. 79, Kosar Alley, Pasdaran Street, West Baharestan Street, Imam Khomeini Street.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8195618888

**Phone**

+98 31 3324 3522

**Fax****Email**

mahdavi88311388@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Mazaheri

**Position**

Associate professor, Director of Persian Medicine Group

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Persian Medicine Group, Amin Hospital, Ibn Sina Street.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8148653141

**Phone**

+98 31 3447 4246

**Email**

Mzaherimohammad@med.mui.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ameneh Parastegari

**Position**

Graduated in general physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No. 79, Kosar Alley, Pasdaran St, West Baharestan St, Imam Khomeini St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8195618888

**Phone**

+98 31 3324 3522

**Fax****Email**

mahdavi88311388@gmail.com

**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@gmail.com and after sending the email, the data will be sent as soon as possible.

**Comments**