

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Design, Formulation, physicochemical evaluation and clinical trial of Gracilaria algae topical cream for treatment of plaque type Psoriasis

Protocol summary

Study aim

Determination about efficacy of Gracilaria algae topical cream in comparison with Clobetasol cream in treatment of plaque type psoriasis

Design

triple blind, randomized controlled clinical trial with a group design of 30 patients enrolled between 2019-2020

Settings and conduct

30 patients who has been visited Alzahra and Sedighe Tahere dermatology clinics will be the population of interest. One person out of study who is aware of components; allocate A or B code to gracilaria algae or clobetasol creams that patients, investigators, dermatologist and data analyser are unaware of contents of A or B creams. patients who have met all of the following criteria of study; have been asked to use topical creams of Gracilaria algae and clobetasol which is allocated randomized A or B code to them to one of the left or right symmetric plaques once daily for 2 months; also not using another treatment of psoriasis during study.

Participants/Inclusion and exclusion criteria

inclusion criteria: mild to moderate plaque type psoriasis; less than 20 percent body involvement with at least 2 symmetric plaques; age between 20 to 60 exclusion criteria: pregnancy; lactation; liver and kidney failure

Intervention groups

patients who have met all of the following criteria of study; have been asked to use topical creams of Gracilaria algae and clobetasol which is allocated randomized A or B code to them to one of the left or right symmetric plaques once daily for 2 months; also not using another treatment of psoriasis during study.

Main outcome variables

Psoriasis area and severity index(PASI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191112045423N1**

Registration date: **2020-01-31, 1398/11/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-31, 1398/11/11**

Update count: **0**

Registration date

2020-01-31, 1398/11/11

Registrant information

Name

Mohammad Ali Shahtalebi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3465 0038

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safoorbk@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-14, 1398/09/23

Expected recruitment end date

2020-03-13, 1398/12/23

Actual recruitment start date

2019-12-20, 1398/09/29

Actual recruitment end date

2020-03-19, 1398/12/29

Trial completion date

2020-03-19, 1398/12/29

Scientific title

Design, Formulation, physicochemical evaluation and clinical trial of Gracilaria algae topical cream for treatment of plaque type Psoriasis

Public title

Effect of topical cream of Gracilaria algae in treatment of plaque type Psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Mild to moderate plaque type psoriasis include atleast 2 symetric plaques involvement of less than 20 percent of body surface age limitation between 20 to 60 years old free and informed written consent for participating in study

Exclusion criteria:

Pregnancy Lactation Renal Failure Hepatitis and Liver Failure Concurrent systemic treatment indication

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

at least 2 symmetric plaques in each individual

Actual sample size reached: **30**

More than 1 sample in each individual

Actual sample size in each individual: **2**

2 plaques larger than 2 cm x 2 cm size and maximum 15 cm x 15 cm size with at least 5 cm distance between 2 plaques.

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method is done with Saghayi randomization software for each symmetric plaques in each person randomly allocate different side of plaques (left or right) to treatment drug(Clobetasol cream) and interventional drug(Gracilaria algae topical cream) which is allocated A or B code to them in blinding description.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After design and formulation of Clobetasol creams and Gracilaria algae topical creams which are similarized for Organoleptic properties like color and odor, they will be packaged in same containers. One person out of study will dedicate A or B code to Clobetasol creams or Gracilaria algae topical creams while participants, investigators, Dermatologist and data analyzer are not aware of content of A or B creams during study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research and Technology Deputy of Isfahan University of Medical Sciences

Street address

Research and Technology Deputy of Isfahan University of Medical Sciences, Hezar Jerib Avenue, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-12-14, 1398/09/23

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.519

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

Plaque type Psoriasis

ICD-10 code

L40.8

ICD-10 code description

Other psoriasis

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

PASI(psoriasis area and severity index)

Timepoint

4 and 8 weeks after using creams

Method of measurement

Dermatologist opinion based on PASI score

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: gracilaria algae topical cream 3%

which is made in Dr.Shahtalebi laboratory in Isfahan,once daily for 2 months,topical,one of the symmetric plaques in each patients consider intervention group.

Category

Treatment - Drugs

2

Description

Control group: clobetasol topical cream 0.05%,once daily for 2 months,topical,one of the plaques in each patients consider control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin Diseases and Leishmaniasis Research Center

Full name of responsible person

Dr. Zabihollah Shahmordi

Street address

Hazrat Sedighe Tahereh Complex, Khorram Ave, Isfahan

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Dr. Mohammad ali shahtalebi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Pharmacy and Pharmeceutical Sciences, Hezar Jerib Avenue, Isfahan

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Full name of responsible person

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professor

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Web page address**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

Deidentified Ipd collected for the primary outcome
related to study will be published.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

Descriptive analysis is allowed to report on data if
available

From where data/document is obtainable

Safoora Bokaie; Iran; Isfahan; Isfahan university of
medical science; Pharmacy and pharmaceutical science
school; email:safoorbk@ymail.com

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

The request is discussed in the Center Committee and
after approval, the data is submitted to the applicant
over a period of approximately one month.

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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mohammad ali shahtalebi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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