

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Preparation & evaluation of Topical Rosuvastatin & Melatonin vs placebo in Patients with Mild to Moderate Plaque Psoriasis! A Randomized Double-blinded Clinical Trial

Protocol summary

Study aim

Preparation of melatonin and rosuvastatin creams and comparing their clinical effects on psoriasis patients

Design

51 patients aged 18 years and older, with a clinical diagnosis that fills the morphological criteria of stable psoriasis plaque, enter the study with plaques size 100 cm² or less. If eligible, patients will be randomized according to a table of random numbers to receive one of the interventions of melatonin or rosuvastatin or placebo creams (17 in each group). Patients, clinical evaluators, and physicians will be blinded by the type of intervention. Before entering the study, all patients undergo a four-week wash-out course of any topical product associated with psoriasis. In addition, systemic therapies, including phototherapy, will be discontinued four weeks before the study. Patients are instructed to use their group's topical cream twice a day and not to use any other moisturizers when using the cream. The amount of cream used in patients is the same as the fingertip unit (FTU), twice a day, which is one use at bedtime. After treatment, patients are monitored for plaque recurrence for 8 weeks.

Settings and conduct

Yazd Rheumatology Specialist Office

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients were 18 years or older; less than 10% body surface area
Exclusion criteria: Pregnancy; sensitivity to the components of the cream are the conditions

Intervention groups

One group is the Melatonin cream recipient, the other is Rosuvastatin cream, and the last is the placebo cream recipient.

Main outcome variables

Psoriasis Area Severity Index (PASI) : Dermatological Sum Score (DSS) : Dermatology Life Quality Index (DLQI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190810044500N16**

Registration date: **2021-06-13, 1400/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-13, 1400/03/23**

Update count: **0**

Registration date

2021-06-13, 1400/03/23

Registrant information

Name

Fatemeh Saghafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3419

Email address

f.saghafi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preparation & evaluation of Topical Rosuvastatin & Melatonin vs placebo in Patients with Mild to Moderate Plaque Psoriasis: A Randomized Double-blinded Clinical Trial

Public title

Preparation & evaluation of Topical Rosuvastatin & Melatonin vs placebo in Patients with Mild to Moderate Plaque Psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18 years and older Less than 10% body surface area (BSA)

Exclusion criteria:

Pregnancy Sensitivity to cream components

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

First, using Random allocation software (version 1.0), we generate a random sequence by a simple random allocation method. In this table, we specify from 1 to 51 and each number is assigned to an intervention group (A or B or C). The first eligible person is referred to as number 1, the second person as number 2, and so on up to 51 patients. To be blind to random allocation, patients are placed in one of the intervention groups (A or B or C) according to the table by a third person who is unaware of the interventions.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, clinical evaluators, and physicians will be blinded by the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University Medical Sciences

Street address

Shahid Sadoughi university of medical sciences, Professor Hesabi Blvd, Yazd, Iran

City

yazd

Province

Yazd

Postal code

8915173143

Approval date

2020-11-09, 1399/08/19

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.221

Health conditions studied

1

Description of health condition studied

Psoriasis

ICD-10 code

L40

ICD-10 code description

Psoriasis

Primary outcomes

1

Description

Psoriasis Area Severity Index

Timepoint

Weeks 0, 4, 8

Method of measurement

Score 0_72

Secondary outcomes

1

Description

Dermatological Sum Score (DSS)

Timepoint

Weeks 0,4,8

Method of measurement

Based on a scale of 4 points (0: absent,1: mild, 2: moderate, 3: severe)

2

Description

Dermatology Life Quality Index (DLQI)

Timepoint

weeks 0,4,8

Method of measurement

Based on the questionnaire

Intervention groups

1

Description

Intervention group: Patients will use 5% melatonin cream twice daily for 8 weeks

Category

Treatment - Drugs

2

Description

Intervention group: Patients will use 5% rosuvastatin cream twice daily for 8 weeks

Category

Treatment - Drugs

3

Description

Control group: Patients will use placebo cream twice daily for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Rheumatology Specialist Office

Full name of responsible person

Dr. Hossein Soleimani Salehabadi

Street address

Taleghani St., Mojahedin Alley, after Razi Doctors Building

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8916978477

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h.soleimani@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

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mmirzaei@ssu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Saghafi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Position

Associate professor

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)

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