Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 were18 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)

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+98 35 3820 3419

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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 Commitee of Shahid Sadoughi University Medical Sciencrs
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
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8916978477
Phone
+98 35 3146 2056
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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
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Person responsible for scientific inquiries

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Associate professor

Latest degree

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Other areas of specialty/work

Medical Pharmacy

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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