Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Assessing effectiveness of adding topical atorvastatin 1% ointment to topical calcineurin inhibitor treatment for nonsegmental vitiligo patients visited at Afzalipour hospital dermatology clinics

Protocol summary

Study aim
Determining and comparing treatment effectiveness in the two arms of trial according to VASI, and associations with age, gender, family history, disease duration, vitiligo type and disease location, side effects, patients' satisfaction, and possible associations between any abnormal laboratory result and treatment type in the two arms of trial.

Design
Two arms, parallel groups, randomized controlled, triple blinded clinical trial

Settings and conduct
The stusy will be done on 20 patients visited at Kerman Afzalipour Hospital dermatology clinic. Patients will be randomly allocated into two arms and will receive either neosomal atorvastatin 1% oint or placebo oint, plus neosomal tacrolimus oint twice daily for 3 months.

Participants/Inclusion and exclusion criteria
Inclusion criteria Diagnosis of nonsegmental vitiligo made by the attending dermatologist Age of at least 18 years at the start of the study Male or nonpregnant, nonbreastfeesing female Noninclusion/exclusion criteria Any other cutaneous or internal disease Segmental vitiligo Pregnancy or breastfeeding History of any type of hypersensitivity reaction to atorvastatin Statin use in the previous 8 weeks Systemic immunosuppressive or immunomodulator therapy (steroids, cyclosporin A) in the previous 4 weeks or using azathioprine, mycophenolate mofetil, methotrexate, or janus kinase inhibitors in the previous 8 weeks Phototherapy in the previous 4 weeks Alcohol or drug abuse History of cutaneous malignancy in the recent 5 years or having a current cutaneous malignancy Participafing in any other clinical trial Noncompliant patient

Intervention groups
Intervention: neosomal atorvastatin 1% oint plus neosomal tacrolimus oint. Control arm: placebo oint plus neosomal tacrolimus oint.

Main outcome variables
VASI change

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200714048099N1**
Registration date: **2020-08-30, 1399/06/09**
Registration timing: **prospective**

Last update: **2020-08-30, 1399/06/09**
Update count: **0**

Registration date
2020-08-30, 1399/06/09

Registrant information

Name
Hamed Zartab

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-05-22, 1400/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing effectiveness of adding topical atorvastatin 1% ointment to topical calcineurin inhibitor treatment for nonsegmental vitiligo patients visited at Afzalipour hospital dermatology clinics

Public title
Assessing effectiveness of adding topical atorvastatin to vitiligo treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A diagnosis of non-segmental vitiligo made by the attending dermatologist who first visits patient at the Afzalipour Hospital's dermatology clinic Filling out and signing the written informed consent form by the patient Patient's age of at least 18 years at the time of signing the informed consent Male or nonpregnant and nonbreastfeeding female
Exclusion criteria:
Any dermatologic disorder other than vitiligo; infectious disorders; inflammatory disorders; diabetes mellitus; cardiovascular disorders; renal disorders; liver disorders; endocrinologic disorders; autoimmune disorders; any other uncompensated medical disorder A diagnosis of segmental vitiligo made by the attending dermatologist who initially visits patient Pregnancy or breastfeeding History of hypersensitivity to atorvastatin Using any type of drugs of statin group during the 8 week period immediatly before starting the trial Using systemic immunosuppressive or immunomodulator treatments (cyclosporin A, corticosteroids) during the 4 week period immediatly before starting the trial or using azathioprine, methotrexate, mycophenolate mofetil, or janus kinase inhibitors during the 8 week period immediatly before starting the trial Phototherapy as a treatment of vitiligo or any other disorder during the 4 week period immediatly before starting the trial Alcohol or illicit drug use History of dermatologic malignancy during the 5 year period immediatly before starting the trial or current dermatologic malignancy Being involved in any other clinical trial Noncompliant patient
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Using table of random numbers, 10 patients will be allocated to each of the intervention and control groups. The intervention group will receive neosomal atorvastatin 1% oint and topical neosomal tacrolimus treatments. The control group will receive placebo oint and topical neosomal tacrolimus treatment. Each participant will be given a number from 1 to 20. One row and one column will be randomly chosen from the table of random numbers; the intersection between this row and column will be the starting point for sampling. A finger will be put on the starting point and will be moved downwards through the table. Because there should be 10 participants in the intervention group and 10 participants in the control group, the two digits at the right side of each number in the table will be considered. The moving of finger will be repeated until 10 participants of the intervention group will be chosen. Duplicate numbers and numbers larger than 20 will not be considered. In this way, it will be found out that which 10 numbers among all of the 20 numbers given to the whoke participants will be allocated to the intervention group (e.g. numbers 3, 4, 9, 11, 13, 14, ...). The remaining 10 participants will be automatically put in the control group. After randomization, each of the 20 numbers will be matched with one of the treatment arms. Each treatment arm will be allocated the letter A or B and these letters will be put in an opaque and sealed pocket. Each patient will receive her/his treatment based on the allocated pocket. The only peron who is aware of the allocated arm will be the operator who will not be involved in other part of the trial.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Letters A or B will be allocated to each treatment arm. The only person aware of what treatment is specified to each of the groups will be the operator who will be responsible for handing in the treatments to the patients. Patients, physicians and the analyzer of the final data will not be aware of the content of groups A and B.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Kerman University of Medical Sciences

Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Postal Code: 7616913555, Iran
City
Kerman
Province
Kerman
Postal code
7616913555

Approval date
2019-11-24, 1398/09/03

Ethics committee reference number
IR.KMU.AH.REC.1398.132

Health conditions studied

1

Description of health condition studied
Vitiligo

ICD-10 code
L80

ICD-10 code description
Vitiligo

Primary outcomes

1

Description
Vitiligo Area Scoring Index (VASI)

Timepoint
At the beginning of the study (before any intervention) and 3 months after the start of study interventions.

Method of measurement
VASI is defined as the product of hand units (each hand unit equals 1% body surface area involvement) times depigmentation pattern in each measured area.

Secondary outcomes

1

Description
Treatment side effects

Timepoint
Throughout study period and up to 3 months after the start of the study.

Method of measurement
History taking and physical exam

2

Description
Patient's satisfaction

Timepoint
Three months after the start of the study

Method of measurement
Asking patient to score her/his satisfaction on a scale of 0 to 10

3

Description
Any association between laboratory abnormalities and treatment type

Timepoint
At the beginning and at the end of the study (3 months after start of the study)

Method of measurement
Blood test and measuring serum levels of variables

Intervention groups

1

Description
Control group patients will receive a topical placebo oint (similar in appearance to neosomal atorvastatin 1% oint) together with topical neosomal tacrolimus oint to be used twice daily for 3 months.

Category
Treatment - Drugs

2

Description
Intervention group will receive topical neosomal atorvastatin 1% oint together with topical neosomal tacrolimus oint to be used twice daily for 3 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Afzalipour Hospital dermatology clinic
Full name of responsible person
Rezvan Amiri
Street address
Afzalipour Hospital, Imam Khomeini Highway
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person

Abbas Pardakhty

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Grant name

Grant code / Reference number

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

Title of funding source
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Rezvan Amiri

Position
Assistant Professor of Dermatology

Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There are no more information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available