Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of fluocinolone drug with oral atorvastatin with fluocinolone alone on the treatment of patients with vitiligo

Protocol summary

Study aim

Comparison of the effect of fluocinolone drug with oral atorvastatin with fluocinolone alone on the treatment of patients with vitiligo

Design

A clinical trial with a control group, with parallel groups, one-way blind, randomized, on 40 patients (2 groups of 20 people). Excel software rand function was used for randomization. We will construct 6 blocks in AABB, BBAA, ABAB, BABA, ABBA, and BAAB using four blocks. We will assign 1 to 6 for each block. Then, using the random number table, based on the sample size, 10 units of 4 blocks will be selected so that we consider having 20 people in the group (A) and 20 people in the group (B). Therefore, we will do block randomization.

Settings and conduct

Kowsar Hospital Clinic. Given that patients are coded by the clinical caregiver. Researchers are unaware of the type of grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20-60 years; Infection of less than 20% of the body surface with vitiligo; Vitiligo over the past year. Exclusion criteria: Pregnant or lactating woman; With systemic and metabolic diseases (diabetes, thyroid diseases, etc.).

Intervention groups

Intervention group: Patients receive topical (fluocinolone ointment 0.025% - Darupakhsh Company) twice daily for 12 weeks. They also take atorvastatin 20 mg tablets(Rosdaro Company) for 12 weeks (one tablet daily for the first month and two tablets daily for the second month). Control group: Patients receive routine treatment (fluocinolone ointment %0.025 - Darupakhsh Company) topical for 12 weeks and twice a day.

Main outcome variables

The severity of the disease.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N64**
Registration date: **2021-02-12, 1399/11/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-12, 1399/11/24**
Update count: **0**

Registration date

2021-02-12, 1399/11/24

Registrant information

Name
Alireza Emadi
Name of organization / entity
Semnan University of Medical Sciences, Semnan, Iran
Country
Iran (Islamic Republic of)
Phone
+98 23 3345 1336
Email address
are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of fluocinolone drug with oral atorvastatin with fluocinolone alone on the treatment of patients with vitiligo

Public title
Comparison of the effect of fluocinolone drug with oral atorvastatin on the treatment of patients with vitiligo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 20-60 years Infection of less than 20% of the body surface with vitiligo Vitiligo over the past year
Exclusion criteria:
Pregnant or lactating woman With systemic and metabolic diseases (diabetes, thyroid diseases, etc.)
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
We will construct 6 blocks in AABB, BBAA, ABAB, BABA, ABBA, and BAAB using four blocks. We will assign 1 to 6 for each block. Then, using the random number table, based on the sample size, 10 units of 4 blocks will be selected so that we consider having 20 people in the group (A) and 20 people in the group (B). Therefore, we will do block randomization.
Blinding (investigator's opinion)
Single blinded
Blinding description
Given that patients are coded by the clinical caregiver. researchers are unaware of the type of grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences
Street address
Semnan University of Medical Sciences, Basij Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2020-08-25, 1399/06/04
Ethics committee reference number
IR.SEMUMS.REC.1399.165

Health conditions studied

1

Description of health condition studied
Vitiligo
ICD-10 code
L80
ICD-10 code description
Vitiligo

Primary outcomes

1

Description
The severity of the disease
Timepoint
Before intervention, 1 and 2 months after intervention
Method of measurement
Scoring using the vitiligo area severity index (VASI) and clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Patients receive routine treatment (fluocinolone ointment %0.025 - Darupakhsh Company) topical for 12 weeks and twice a day.
Category
Diagnosis

2

Description
Intervention group: Patients receive topical (fluocinolone ointment 0.025% - Darupakhsh Company) twice daily for 12 weeks. They also take atorvastatin 20 mg tablets(Rosdaro Company) for 12 weeks (one tablet daily for the first month and two tablets daily for the second month).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kowsar Hospital
Full name of responsible person
Maryam Azizzadeh
Street address
Street Amin, Semnan
City
Semnan
Province
Semnan
Postal code
3519899951
Phone
+98 23 3345 1336
Email
are20935@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Parviz Kokhaie
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan.
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
P_kokha@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Maryam Azizzadeh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Skin and hair
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan.
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
are20935@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Maryam Azizzadeh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Skin and hair
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan.
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
are20935@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Maryam Azizzadeh

Position
Associate professor
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Skin and hair
Street address
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Province
Semnan
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Email
are20935@gmail.com

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
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