

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 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

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Email

are20935@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

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Latest degree

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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

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