

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

A comparative study on the therapeutic effect of combined NBUVB (Narrow Band Ultraviolet B) and systemic Simvastatin with NBUVB alone in patients with vitiligo

Protocol summary

Study aim

The effect of phototherapy and oral Simvastatin in comparison with phototherapy alone in the treatment of patients with vitiligo

Design

This study is a phase 3 randomized, double-blind, randomized clinical trial. A total of 50 patients will be selected from the dermatology clinic of Shahid Faghihi Hospital in Shiraz. Sample size is determined using NCCS software, 90% power and first type error 5% and using the same previous article. The studied patients are randomly divided into two groups of intervention and control through block randomization. Statistical methods of analysis are the results of independent t-test - Chi-square test.

Settings and conduct

Shahid Faghihi Clinic, Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Patients with vitiligo who have just started treatment and have not taken medication in the last 6 months.

Intervention groups

Simvastatin 20 mg drug made by Iranian company Poursina (first month 2 times a day in the second month 3 times a day in the third and fourth month 4 times a day) And placebo (made by Shiraz School of Pharmacy) similar to Simvastatin.

Main outcome variables

-Lesion healing rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191013045092N2**

Registration date: **2021-01-01, 1399/10/12**

Registration timing: **retrospective**

Last update: **2021-01-01, 1399/10/12**

Update count: **0**

Registration date

2021-01-01, 1399/10/12

Registrant information

Name

Ladan Dastgheib

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3231 9049

Email address

dastghl@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-10-16, 1394/07/24

Expected recruitment end date

2016-03-13, 1394/12/23

Actual recruitment start date

2015-10-16, 1394/07/24

Actual recruitment end date

2016-03-13, 1394/12/23

Trial completion date

2016-03-13, 1394/12/23

Scientific title

A comparative study on the therapeutic effect of combined NBUVB (Narrow Band Ultraviolet B) and systemic Simvastatin with NBUVB alone in patients with vitiligo

Public title

A comparative study on the therapeutic effect of combined NBUVB and systemic Simvastatin with NBUVB alone in patients with vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have just started treatment and have not taken medication in the last 6 months

Exclusion criteria:

Patients with liver and kidney problems Pregnant or breastfeeding Patients taking simvastatin interfering drug Under 16 years old

Age

From **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are referred to a secretary to be blindly assigned to one of the two groups A and B based on block randomization. Drugs are provided to patients in sealed paper bags on a monthly basis. 2 times a day for the second month (3 times a day and the third and fourth months 4 times a day) and the second group of patients on placebo (made by Shiraz School of Pharmacy).

Blinding (investigator's opinion)

Double blinded

Blinding description

Informed consent will be taken from the participants and they don't know that they are receiving drug or placebo. the investigator and the care giver don't know the intervention and placebo group

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical sciences

Street address

Shiraz, Zand street, medical university, ethics committee

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2016-07-01, 1395/04/11

Ethics committee reference number

IR.SUMS.REC.1395.S257

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Investigation of skin re-pigmentation rate

Timepoint

Months 1, 2, 3 and 4

Method of measurement

Repetition of experiments, photography and scoring

Secondary outcomes

empty

Intervention groups

1

Description

The first group of simvastatin 20 mg made by Iranian company Poursina (first month 2 times a day in the second month 3 times a day in the third and fourth month 4 times a day) and the placebo group (made by Shiraz School of Pharmacy) similar to the first month of simvastatin twice a day and then 3 times a day The third and fourth months are used 4 times a day. Similar to simvastatin, the first month is used twice a day and then 3 times a day and the third and fourth months 4 times a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Light therapy department of Shahid Faghihi clinic,
Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ladan Dastgheib

Street address

Shiraz, Zand St., Shahid Faghihi Educational and
Medical Center, Dermatology Clinic, third floor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaianzadeh

Street address

Shiraz, zand street, shiraz university of medical
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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ladan Dastgheib

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Shiraz, Zand street, Shahid faghihi hospital, floor 3,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ladan Dastgheib

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Sara Ranjbar

Position

Research expert

Latest degree

Master

Other areas of specialty/work

Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Article

When the data will become available and for how long

Article publication time

To whom data/document is available

researchers

Under which criteria data/document could be used

In order to raise the scientific level of researchers in this field through articles

From where data/document is obtainable

The executor of the plan

What processes are involved for a request to access data/document

Submit a request, review the executor of the project and send feedback

Comments