Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

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

Protocol summary

Study aim
Determination of the effect of photo-therapy plus Simvastatin tablet in comparison with photo-therapy plus placebo in the treatment of patients with vitiligo referred to Shahid Faghihi Dermatology Clinic

Design
Two arm parallel group randomized clinical trial, double blinded

Settings and conduct
Samples include the patients with vitiligo who refer to the Shahid Faghih Dermatology Clinic. In order to blind the investigator and patients, medications are named as "A" for Simvastatin tablet and B for placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Patients with vitiligo, 2- Involving more than 20% of the body surface, 3- Age above 14 years old. Exclusion criteria: 1- Patients with systemic diseases, 2- Patients who use other therapeutic methods except photo-therapy, 3- Patients with any liver diseases, 4- Patients with any kidney diseases, 5- Pregnant and lactating women, 6- History of allergy to photo-therapy, 7-Taking medication that has interactions with Simvastatin.

Intervention groups
Intervention group: the initial dose of phothotherapy used in every patient is 100 mJ/cm2 and the energy is increased by 10 mJ/cm2 after every dose. The number of treatment sessions of phototherapy has been also determined three times a week. The dose of Simvastatin (manufactured by Pursina Company) is 20 mg with the protocol of the 2 times a day in the first month, 3 times a day in the second month, and 2 tablets twice a day in the third and fourth months. Control group: the initial dose of phothotherapy used in every patient is 100 mJ/cm2 and the energy is increased by 10 mJ/cm2 after every dose. The number of treatment sessions of phototherapy has been also determined three times a week. The dose of placebo (manufactured by Shiraz School of Pharmacy) is similar to dose of prescribed Simvastatin.

Main outcome variables
The amount of melanin pigment in the skin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150825023753N11**
Registration date: **2019-03-30, 1398/01/10**
Registration timing: **retrospective**

Last update: **2019-03-30, 1398/01/10**
Update count: **0**

Registration date
2019-03-30, 1398/01/10

Registrant information

Name
Mohammad Mahdi Parvizi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3212 5592

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parvizim@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-07-22, 1395/05/01

Expected recruitment end date
2017-02-28, 1395/12/10

Actual recruitment start date
2016-07-22, 1395/05/01

Actual recruitment end date
2017-02-28, 1395/12/10

Trial completion date
2017-08-21, 1396/05/30

Scientific title
A comparative study on the therapeutic effect of combined phototherapy and oral Simvastatin with phototherapy alone in patients with vitiligo

Public title
The effect of phototherapy and oral Simvastatin in treatment of vitiligo

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patients with vitiligo Age above 14 years old

Exclusion criteria:
Patients with systemic diseases Patients who use other therapeutic methods except light therapy Patients with any liver disease Patients with any kidney disease Pregnant and lactating women History of allergy to phototherapy Taking medication that has interactions with simvastatin

Age
From **14 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation software Ink was used to create a randomization table

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind the investigator, medications were named A (simvastatin tablet) and B (Placebo). The patients were not aware of which drug they received. The groups were also coded A and B to the statistical analyzer

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Medical School of Shiraz University of Medical Sciences

Street address
Medical School of Shiraz University of Medical Sciences

City
Shiraz

Province
Fars

Postal code
7134845794

Approval date
2016-06-20, 1395/03/31

Ethics committee reference number
IR.SUMS.MED.REC.1395.20

Health conditions studied

1

Description of health condition studied
Vitiligo

ICD-10 code
L80

ICD-10 code description
Vitiligo

Primary outcomes

1

Description
The amount of melanin pigment in the skin

Timepoint
Assessment the amount of melanin pigment at the start of the study and at the end of the first, second, third and fourths month after beginning the treatment

Method of measurement
Vitiligo Area Scoring Index (VASI Score)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The initial dose of phothotherapy used in every patient is 100 mJ/cm2 and the energy is increased by 10 mJ/cm2 after every dose. The number of treatment sessions of phototherapy has been also determined three times a week. The dose of Simvastatin (manufactured by Pursina Company) is 20 mg with the protocol of the 2 times a day in the first month, 3 times a

day in the second month, and 2 tablets twice a day in the third and fourth months

Category

Treatment - Drugs

2

Description

Control group: The initial dose of phothotherapy used in every patient is 100 mJ/cm2 and the energy is increased by 10 mJ/cm2 after every dose. The number of treatment sessions of phototherapy has been also determined three times a week. The dose of placebo (manufactured by Shiraz School of Pharmacy) is 20 mg with the protocol of the 2 times a day in the first month, 3 times a day in the second month, and 2 tablets twice a day in the third and fourth months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Faghihi Dermatology Clinic

Full name of responsible person
Dr. Ladan Dastgheib

Street address
Shahid Faghihi Hospital, Zand street

City
Shiraz

Province
Fars

Postal code
7134846114

Phone
+98 71 3212 5592

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dastghl@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Seyed Basir Hashemi

Street address
Shiraz University of medical Sciences, Research vice, Zand Street

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Grant name

Grant code / Reference number
93-01-01-9021

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

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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

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Person responsible for updating data

Contact
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Full name of responsible person
Dr. Mohammad Mahdi Parvizi
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Other areas of specialty/work
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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
Demographic data and the result of the clinical trial
When the data will become available and for how long
6 month later
To whom data/document is available
Researchers
Under which criteria data/document could be used
After publication of the extracted article of the clinical trial
From where data/document is obtainable
Sending Email to the researchers
What processes are involved for a request to access data/document
Sending the request via the email
Comments