

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation of the effect of Vitilexine Cream Givrelle in comparison with placebo in the treatment of patients with vitiligo undergoing phototherapy

Protocol summary

Study aim

Comparison of the effect of Vitilexin Gyorel and placebo in vitiligo patients undergoing phototherapy

Design

A clinical trial with a control group, with parallel groups, double-blinded, randomized, phase 3 on 66 patients.

Random Allocation software is used for randomization.

Settings and conduct

This study is conducted on patients with vitiligo who are referred to skin clinics of Shiraz University of Medical Sciences. Patients' lesions are randomly divided into two groups (right and left lesions). The plan is implemented in a double-blind manner.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. The patient's age is over 18 years 2. The presence of at least 2 vitiligo corneal lesions in the upper, and lower limbs, face, or trunk that are similar in size and color 3. The disease is under control (non-progressive). 4. Involvement of at least 10% of the body surface 5. Patients are willing to participate in the study. Exclusion criteria: 1. Use of topical medications in the last month 2. Having an immune deficiency 3. Any contraindication for phototherapy such as a history of skin cancer 4. Pregnant and lactating women

Intervention groups

One of the lesions located on one side of the body will receive Vitilexine Cream Givrelle twice a day for three months. Control group: One of the lesions located on the other side of the body will receive a placebo twice a day for three months. Same treatment for both groups: patients will be treated with narrowband ultraviolet B (nb-UVB) three times a week. Phototherapy continues for three months or until the lesions are removed. Each patient is examined and followed up once at the beginning of the treatment and then every one and a half months.

Main outcome variables

Severity of disease using Vitiligo Area Scoring Index (VASI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150825023753N21**

Registration date: **2023-11-15, 1402/08/24**

Registration timing: **prospective**

Last update: **2023-11-15, 1402/08/24**

Update count: **0**

Registration date

2023-11-15, 1402/08/24

Registrant information

Name

Mohammad Mahdi Parvizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3212 5592

Email address

parvizim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-21, 1402/08/30

Expected recruitment end date

2024-05-19, 1403/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Vitilexine Cream Givrelle in comparison with placebo in the treatment of patients with vitiligo undergoing phototherapy

Public title
The effect of Vitilexine Cream Givrelle in comparison with placebo in the treatment of patients with vitiligo undergoing phototherapy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The patient's age is over 18 years The presence of at least 2 vitiligo corneal lesions in the upper, lower limbs, face or trunk that are similar in size and color The disease is under control (non-progressive). Involvement of at least 10% of the body surface Patients willing to participate in the study
Exclusion criteria:
Use of topical medications in the last month Having an immune deficiency Any contraindication for phototherapy such as a history of skin cancer Pregnant and lactating women

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **35**
More than 1 sample in each individual
Number of samples in each individual: **70**
One of the lesions on one side of the body will be selected as intervention and the lesion on the other side will be selected as control

Randomization (investigator's opinion)
Randomized

Randomization description
By using Random Allocation Software, consecutive permutation blocks with the size of 4 lesions in each block are made and the lesions are divided into two groups A (right side) and B (left side). Dark-colored envelopes will be used to hide random allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
To blind the researcher, the drugs are named A (Vitilexine Cream Givrelle) and B (placebo cream). The drug and placebo are similar in terms of shape, color, and consistency. The patient is also not aware of the

type of medicine assigned to him. Also, the groups are coded as A and B and delivered 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

2023-08-12, 1402/05/21

Ethics committee reference number

IR.SUMS.MED.REC.1402.208

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Severity of vitiligo

Timepoint

Before the intervention, 6 weeks later, 12 weeks later

Method of measurement

Vitiligo Area Scoring Index (VASI)

Secondary outcomes

empty

Intervention groups

1

Description

One of the lesions located on one side of the body will receive Vitilexine Cream Givrelle twice a day for three months. Also, patients will be treated with narrowband ultraviolet B (nb-UVB) three times a week. The initial dose of radiation will be determined between 0.5 and 1 J/cm² based on the lesions and the skin type of the patients, and then the radiation dose will be increased based on whether or not stable erythema occurs (every week by 0.1 J/cm²). In cases of long-term irritation or erythema, the radiation dose is reduced by 0.1 J/cm², and when the irritation is removed, the dose will increase again by 0.1 J/cm². In each session before the start of phototherapy, the related complications are examined, and phototherapy continues for three months or until the lesions are removed. Each patient is examined and followed up once at the beginning of the treatment and then every one and a half months. At the end of a month and a half and three months later, the lesions are photographed again.

Category

Treatment - Drugs

2

Description

Control group: One of the lesions located on one side of the body will receive placebo twice a day for three months. Also, patients will be treated with narrowband ultraviolet B (nb-UVB) three times a week. The initial dose of radiation will be determined between 0.5 and 1 J/cm² based on the lesions and the skin type of the patients, and then the radiation dose will be increased based on whether or not stable erythema occurs (every week by 0.1 J/cm²). In cases of long-term irritation or erythema, the radiation dose is reduced by 0.1 J/cm², and when the irritation is removed, the dose will increase again by 0.1 J/cm². In each session before the start of phototherapy, the related complications are examined, and phototherapy continues for three months or until the lesions are removed. Each patient is examined and followed up once at the beginning of the treatment and then every one and a half months. At the end of a month and a half and three months later, the lesions are photographed again.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Faghihi Dermatology Clinic
Full name of responsible person
Dr. Nasrin Saki
Street address

Shahid Faghihi Hospital, Zand Avenue
City
Shiraz
Province
Fars
Postal code
71348466114
Phone
+98 71 3212 5592
Email
nasrinsa85@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hashem Hashempur

Street address

7th floor, Vice Chancellor of Research, Shiraz
University of Medical Sciences, Zand Blvd., Shiraz,
Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

vcrdep@sums.ac.ir

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. Samaneh Yekran

Position

Dermatology resident
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Zand Ave, Shahid Faghihi Hospital,
City
Shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3212 5592
Email
s_yekran@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Nasrin Saki
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Zand Ave, Shahid Faghihi Hospital,
City
Shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3212 5592
Email
nasrinsa85@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Mahdi Parvizi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work

Dermatology
Street address
Zand Ave, Shahid Faghihi Hospital,
City
Shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3212 5592
Email
mmparvizi@gmail.com

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

One year later

To whom data/document is available

Researchers

Under which criteria data/document could be used

After the publication of the article based on the clinical trial, it will be possible to share the data. The recipients of the data can use the data by obtaining permission from the project managers. The managers of this project will allow the data to be used in secondary data analysis studies and systematic reviews.

From where data/document is obtainable

Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.

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

Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.

Comments

Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.