

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of the additive effect of topical psoralen with ultraviolet A (PUVA) phototherapy after suction blister epidermal grafting surgery in patients with acral vitiligo

Protocol summary

Study aim

Determination of the additive effect of topical psoralen with ultraviolet A (PUVA) phototherapy after suction blister epidermal grafting surgery in patients with acral vitiligo

Design

Phase 3, parallel group, clinical trial, with consecutive sampling, including 20 patients, single blinded, computerized randomized with permuted blocks

Settings and conduct

The study is conducted in the Imam Reza laser clinic of Shiraz University of Medical Sciences with suction blister epidermal grafting surgery for treatment of vitiligo on the dorsa of hands or feet in both groups. In each patient only one side undergoes topical psoralen with ultraviolet A (PUVA) phototherapy randomly (Twice weekly for 6 months), besides the graft, and the other side is not treated with phototherapy. The patients are assessed at the beginning of treatment, months 1,2,4, and 6 by photography. The investigator is blind to the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Acral vitiligo; 18 years of age and higher; Bilateral lesions; Stable vitiligo in the past 6 months; Ability to refer for phototherapy; Minimum size of 1*1 cm; Maximum size of 3*3 cm Exclusion criteria: History of keloid; Treatment for vitiligo in the past one month; Poor wound healing; Consumption of anticoagulant drugs; Consumption of immunosuppressant drugs; Pregnancy; Lactation

Intervention groups

Suction blister epidermal grafting surgery with topical psoralen with ultraviolet A (PUVA) phototherapy in one side hand or foot (Twice weekly for 6 months)

Main outcome variables

Reversal of normal skin pigment, measured by Reverse Vitiligo Area Severity Index (VASI), and Vitiligo Extent

Score for a Target Area (VESTA)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140212016557N9**

Registration date: **2021-10-07, 1400/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-07, 1400/07/15**

Update count: **0**

Registration date

2021-10-07, 1400/07/15

Registrant information

Name

Mozhdeh Sepaskhah

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparison of the additive effect of topical psoralen with ultraviolet A (PUVA) phototherapy after suction blister epidermal grafting surgery in patients with acral vitiligo

Public title
Effect of skin graft with and without phototherapy in the treatment of acral vitiligo

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acral vitiligo 18 years of age and higher Bilateral lesions Stable vitiligo in the past 6 months Ability to refer for phototherapy Minimum size of 1*1 cm Maximum size of 3*3 cm

Exclusion criteria:

History of keloid Treatment for vitiligo in the past one month Poor wound healing Consumption of anticoagulant drugs Consumption of immunosuppressant drugs Pregnancy Lactation

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants were randomized using permuted block randomization (size of each block: 4), in individual units, using random allocation software. The output of software is a table that determines the right or left side undergoes phototherapy.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the different treatment methods in two sides, the participants cannot be blinded. Principle investigator, and care provider physician are also aware of the the side undergoing phototherapy. But, outcome assessors are not aware of the side undergoing phototherapy in each patient.

Placebo
Not 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 University of Medical Sciences, Zand St., Shiraz. Iran

City

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Province

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Postal code

7134845794

Approval date

2021-08-19, 1400/05/28

Ethics committee reference number

IR.SUMS.MED.REC.1400.265

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Reversal of normal skin pigment

Timepoint

Months 1, 2, 4, and 6

Method of measurement

Reverse Vitiligo Area Severity Index (VASI), which measures the percentage of pigment reversal.

2

Description

Vitiligo Extent Score for a Target Area (VESTA)

Timepoint

Months 1, 2, 4, and 6

Method of measurement

A formula that considers fully repigmented area, remaining area, and perifollicular repigmentation in the remaining area.

Secondary outcomes

1

Description

Time of pigment reversal

Timepoint

Months 1, 2, 4, and 6

Method of measurement

Measurement of the numbers of weeks to achieve 50% pigment reversal

2

Description

Color match

Timepoint

Months 1, 2, 4, and 6

Method of measurement

Difference of the lesion color with surrounding normal skin color measured by colorimetric device

3

Description

Quality of Life

Timepoint

At the beginning and end of treatment

Method of measurement

Vitiligo Quality of Life index (VitiQoL)

4

Description

Patient satisfaction

Timepoint

At the end of treatment

Method of measurement

Three questions with answers from 0 to 10

Intervention groups

1

Description

Intervention group: Suction blister epidermal grafting surgery with topical psoralen with ultraviolet A (PUVA) phototherapy in one side hand or foot (Twice weekly for 6 months)

Category

Treatment - Surgery

2

Description

Control group: Suction blister epidermal grafting surgery without topical psoralen with ultraviolet A (PUVA) phototherapy in one side hand or foot

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Laser clinic, Imam Reza clinic

Full name of responsible person

Mozhdeh Sepaskhah

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Laser clinic, Imam Reza clinic, Namazi Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Research grant of the Research Council of Shiraz University of Medical Sciences

Grant code / Reference number

23448

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
Amirhossein Heydarnejad
Position
Resident
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Other areas of specialty/work
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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable