

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of combination treatment by co 2 fractional laser on the margin of lesions and Narrow Band Ultraviolet Band in vitiligo patients referred to Shohada-e- Tajrish and Loghman-e - Hakim hospitals during years 1394- 1396

Protocol summary

Summary

This is a study on patients with vitiligo, to compare the effect of combination therapy of fractional carbon dioxide laser in margin of lesions, in association with narrow band ultraviolet band (NBUVB), and NBUVB alone. The research is a nonrandomized Clinical trial and the study population are 18 to 60 years old vitiligo patients whom their disease is diagnosed by a Dermatologist, and they were not received any treatment during last 3 months. The number of patients is 30. the lesions with 2 to 5 cm in diameter are selected and divided into two part; right and left. The treatment method is, Korean MIXEL DIOD Laser with 10 to 20 mj energy was used in the 1cm margin of each lesion in one side. One week after laser, the Patient will exposed to NBUVB in standard Walkman's cabin with 3 times weekly. Primary energy was 0/1 to 0/2 j/ cm², and according to patient's skin tolerance and Treatment response it will be increased to 2j/cm² gradually and will continues for 6 months. In the other side of lesions NBUVB will be applied. The patients will be assessed every month until end of forth and sixth month, and the severity of disease and the treatment response will be assessed by VASI (Vitiligo Area and Severity Index) scoring. During the study, pictures will be taken by standard camera and will be shown to 2 blinded dermatologists to assess the pigmentation rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031627072N1**

Registration date: **2016-05-19, 1395/02/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-19, 1395/02/30

Registrant information

Name

Sara Ghasemloo

Name of organization / entity

Skin Research center

Country

Iran (Islamic Republic of)

Phone

+98 22741507

Email address

sara_ghasemloo@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2016-01-28, 1394/11/08

Expected recruitment end date

2016-10-20, 1395/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of combination treatment by co 2 fractional laser on the margin of lesions and Narrow Band Ultraviolet Band in vitiligo patients referred to Shohada-e- Tajrish and Loghman-e - Hakim hospitals during years 1394- 1396

Public title

The combination of NBUVB, co2 fractional laser treatment of vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Patients who entered the study were personal satisfaction. 2. under the age of 60 years and more than 18 years. 3 patients (based on the detection dermatologist) with vitiligo . Exclusion criteria: 1. a history of allergy to the sun or UV radiation . 2. person or family history of skin cancer. 3. pregnancy and lactation. 4. ANA test is positive. 5. Fitzpatrick skin type 1. 6. Enable infection or history of skin infection with HSV. 7. Hypertrophic scars or keloids . 8. Heart failure. 9. Patients whit or a history of atypical nevus and melanoma. 10. Patients whit local or systemic treatment during the last three months .

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Arab street next Shahid Ayatollah Taleghsni Hospital, Highway Chamran Street Yemen, Tehran

City

Tehran

Postal code

Approval date

2016-02-27, 1394/12/08

Ethics committee reference number

Ir.sbm.u.SRC.REC.1394.14

Health conditions studied

1

Description of health condition studied

VITILIGO

ICD-10 code

L80

ICD-10 code description

VITILIGO

Primary outcomes

1

Description

The efficacy of co2 Fractional laser and NBUVB of pigmentation of vitiligo lesions

Timepoint

Monthly until the end of the fourth month and at the end of the sixth month

Method of measurement

Disease severity index based on VASI

Secondary outcomes

1

Description

Side effects

Timepoint

Disease severity index based on VASI

Method of measurement

Ask the patient

Intervention groups

1

Description

Case: The treatment method is, Korean MIXEL, DIOD Laser with 10 to 20 m j energy was used in the 1 cm margin of each lesion in one side. One week after laser, the Patient will exposed to NBUVB in standard Walkman's cabin with 3 times weekly. Primary energy was 0/1 to 0/2 j/ cm 2, and according to patient's skin tolerance and Treatment response it will be increased to 2 j/cm 2 gradually and will continues for 6 months

Category

Treatment - Devices

2

Description

Control: to NBUVB in standard Walkman's cabin with 3 times weekly. Primary energy was 0/1 to 0/2 j/ cm 2, and according to patient's skin tolerance and Treatment response it will be increased to 2 j/cm 2 gradually and will continues for 6 months.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Sara Ghasemloo

Street address

Shohadaye Tajrish Hospital- Tajrish square -Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Luqman Hakim Hospital

Full name of responsible person

Sara Ghasemloo

Street address

Luqman Hakim Hospital- Makhsoos street-Lashgar
Crossroads

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti
University Skin Research Center of Medical Science

Full name of responsible person

Dr parviz toosi

Street address

Skin Resaerch Center - Shohadaye Tajrish Hospital -
Tajrish square

City

Tehran

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University
Skin Research Center of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Skin Research Center

Full name of responsible person

Sara Ghasemloo

Position

Dermatology Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shohadaye Tajrish Hospital Skin Research Center

Full name of responsible person

Dr Fariba ghalamkarpour

Position

assistant professor

Other areas of specialty/work

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Position

Dermatology resident

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty