Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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.sbmu.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 Ghasrmloo
Street address
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2

Recruitment center
Name of recruitment center
Luqman Hakim Hospital
Full name of responsible person
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Street address
Luqman Hakim Hospital- Makhsoos street-Lashgar Crossroads
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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
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Person responsible for scientific inquiries

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assistant professor
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Person responsible for updating data

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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