Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of using fractional CO2 laser combined with narrow-band ultraviolet B phototherapy vs NB-UVB monotherapy for non-segmental vitiligo

Protocol summary

Study aim

Evaluating the usefulness of fractional CO2 laser combined with narrow band ultraviolet B (UVB) compared to phototherapy with only NB-UVB in the treatment of non-segmental vitiligo.

Design

A clinical trial with a control group, with parallel groups, blinded, randomized, on 15 patients.

Settings and conduct

Study location: Baran Clinic. For each patient, one side of the body is treated with NB-UVB alone, while the other side is treated with combined treatment . a picture will be taken of each patient from both sides of the body before treatment .After treatment, the patient will be evaluated by the doctor. the photo will be taken again. The doctor will not know which side of a patient received phototherapy alone or combined treatment and only evaluates repigmentation

Participants/Inclusion and exclusion criteria

Inclusion criteria: over 18 years old, Non-segmental vitiligo, Has generalized lesions, 3 months have passed since their last treatment, The lesion has been stable during the last year, Exclusion criteria: pregnancy or breastfeeding, History of serious photosensitivity, Suffering from eye cataracts or skin cancer, History of keloid scars.

Intervention groups

All patients will receive phototherapy sessions on both sides of the body 3 times per week for three months . The initial dose of UVB is 240 J/cm2 and each session increases by 20% to achieve the minimum erythema dose. The control group will receive only phototherapy. In the intervention group, simultaneously with phototherapy, three sessions of fractional CO2 laser therapy are performed using a fractional CO2 laser, with energy settings of 10 mJ/cm2 at a penetration depth of 10600 mm, density 25%, frequency 1 time per month and once every time for three months on Vitiligo lesions of left or right side in a randomly manner.

Main outcome variables

repigmentation score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170818035762N5**
Registration date: **2023-03-22, 1402/01/02**
Registration timing: **retrospective**

Last update: **2023-03-22, 1402/01/02**
Update count: **0**

Registration date

2023-03-22, 1402/01/02

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4221 8021

Email address

a.kazeminejad@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of using fractional CO2 laser combined with narrow-band ultraviolet B phototherapy vs NB-UVB monotherapy for non-segmental vitiligo

Public title
Effect of Fractional CO2 laser in treatment of vitiligo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Be over 18 years old suffering from non-segmented vitiligo It has generalized waste (at least 10%). Three months have passed since their last treatment The lesion has been stable during the last year
Exclusion criteria:
Pregnant or breastfeeding Have a history of severe sensitivity to light Have eye cataracts or skin cancer Have a history of keloid scars
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each patient has two samples of vitiligo including one lesion on the right side and another lesion of vitiligo on the left side. One side of the patient's body will be considered as an intervention (phototherapy+laser CO2 fractional) and another one will be considered as a control (phototherapy).
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, two types of treatment are applied to patients. The first treatment includes the combination of phototherapy and laser and the second treatment is phototherapy alone. The first step is to randomize on which side of the patient's body phototherapy and laser will be performed together. First, a number is considered for each patient. From 1 to 15. Then the patients are divided into two groups, even and odd, by throwing a dice. In the next step, they are placed on the basis that, for example, those whose number is even will receive phototherapy treatment on the right side of the body. In this way, the combined laser and phototherapy treatment is performed on the right side of people with odd numbers.
Blinding (investigator's opinion)
Single blinded
Blinding description
To eliminate the interfering effect of the doctor's level of experience and literacy, the treatment phase is performed only by the student and the evaluation phase is performed by the dermatologist. Before the treatment, each patient is photographed from both sides of the body with a camera, from a certain distance, and a certain intensity of the camera light, in a certain and fixed place on each side of the body by the student. Therefore, each patient has one photo for the left side and one photo for the right side before the treatment. After a certain period of treatment for all patients, the patient's evaluation will be done by the doctor. But before the doctor's evaluation, the photo will be taken again with the same conditions mentioned by the student. In fact, there will be 2 pieces of photos for each patient from each side of the body. One picture before the treatment and one picture after the treatment. Therefore, the doctor will not know which side of a patient received phototherapy alone or the combined treatment and only evaluate the repigmentation and reports the changes of two photos
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of mazandaran University of Medical Sciences
Street address
Central Headquarters of Mazandaran University of Medical Sciences,at the beginning of Valiasr Highway,Joibar Three Ways,Imam Square, Sari
City
Sari
Province
Mazandaran
Postal code
۴۸۱۵۷۳۳۹۷۱
Approval date
2022-11-30, 1401/09/09
Ethics committee reference number
IR.MAZUMS.REC.1401.396

Health conditions studied

1

Description of health condition studied
Non segmental vitiligo
ICD-10 code
L80

ICD-10 code description
Vitiligo

Primary outcomes

1

Description
repigmentation score
Timepoint
Before the intervention, and 1 month after the end of the intervention
Method of measurement
Investigating the percentage of repigmentation of vitiligenous lesions

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will include one side of the body of all patients, which will be randomly selected. The selected side will be treated with UVB phototherapy combined with a fractional CO2 laser (for example, if the left side of the patient is selected as the intervention, the right side of that body will be considered control).The selected side as the intervention will be treated with UVB phototherapy for three months. During three months, patients will be subjected to phototherapy three times a week at least one day after the previous time with NB fluorescent tube (DAAVLIN company) with a spectrum of 310-315 nm and a maximum wavelength of 311 nm in a Waldmann UV-100. The initial dose of phototherapy will be 240 J/cm2 and each session will increase by 20% to achieve the minimum erythema dose.In addition to three months of UVB phototherapy on intervention sides, three sessions of fractional CO2 laser therapy on the first phototherapy session of each month will be administrated. Fractional CO2 laser (LUTRUNIC/surgical co2 laser (RF type) (model name: eco2 plus class 4)), with energy settings of 10 mJ/cm2 at a penetration depth of 10600 mm, 25% density. Antiviral pretreatment (valacyclovir 500 mg twice a day for 5 days) was prescribed for the patients and in the first 5 days after the laser session, the patients were asked to avoid using hot water in the treated area.
Category
Treatment - Other

2

Description
Control group: The control group will include one side of the body of all patients, which will be randomly selected. The selected side as control will be treated with phototherapy alone for three months. During three months, patients will be subjected to phototherapy three times a week at least one day after the previous times with NB fluorescent tube (DAAVLIN company) with a spectrum of 310-315 nm and a maximum wavelength of 311 nm in a Waldmann UV-100. The initial dose of phototherapy will be 240 J/cm2 and each session will increase by 20% to achieve the minimum erythema dose.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baran Skin Clinic
Full name of responsible person
Dr.Ghasem Rahmatpour
Street address
Baran Skin Clinic,15 Khordad ST,Sari
City
Sari
Province
Mazandaran
Postal code
4817943559
Phone
+98 11 3325 0450
Email
Dr.rokni@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Pedram Ebrahimnejad
Street address
Mazandaran University of Medical Sciences and Health Services Headquarters, The beginning of Vali Asr Highway, Sari
City
sari
Province
Mazandaran
Postal code
۴۸۱۵۷-۳۳۹۷۱
Phone
+98 11 3304 4000
Email
publicret@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr.Armaghan Kazeminejad
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari
City
Sari
Province
Mazandaran
Postal code
4414733971
Phone
+98 11 3304 4001
Email
A.kazeminejad@mazums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Armaghan Kazeminejad
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari
City
Sari
Province
Mazandaran
Postal code
4414733971
Phone
+98 11 3304 4001
Email
A.kazeminejad@mazums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Armaghan kazeminejad
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari
City
Sari
Province
Mazandaran
Postal code
4414733971
Phone
+98 11 3304 4001
Email
A.kazeminejad@mazums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only part of the data, such as information related to the main outcome or similar, can be shared
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers working in academic and scientific institutions can check the data, perform the statistical analysis they want to match, compare this study with other similar studies, and share the results if necessary.

From where data/document is obtainable

Email to:A.kazeminejad@mazums.ac.ir

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

After communicating by email, data and results will be available if conditions are met

Comments