

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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 nm, 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/cm<sup>2</sup> 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 (LUTRUSIC/surgical co2 laser (RF type) (model name: eco2 plus class 4)), with energy settings of 10 mJ/cm<sup>2</sup> at a penetration depth of 10600 nm, 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/cm<sup>2</sup> 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

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##### 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

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**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

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**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

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**Phone**

+98 11 3304 4001

**Email**

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**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**