Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Comparing and assessment the effects of Fractional CO2 laserr and Microneedling combined with narrowband ultraviolet B and topical steroid for treating non-segmental vitiligo in resistant localizations

Protocol summary

Summary

This study aims to compare the effectiveness of Fractional CO2 Laser and Microneedling, each in combination with Narrowband Ultraviolet B Phototherapy and topical steroid for treatment of generalized vitiligo in resistant localizations. Inclusion criteria are generalized vitiligo patients treated with Narrowband Ultraviolet B Phototherapy for 3 to 6 months but have not improved and those who have the vitiligo patches in bony prominences or end extremities which are resistant to treatment. Exclusion criteria are skin type 1, history of photosensitivity and other conditions that may have risk for patients' interventions. The study population is 80 patients divided into two groups of 40, for random allocation of two types of interventions. For each group, combinations of therapies will be allocated. For the first group the interventional components of combinations are Narrowband Ultraviolet B, fractional CO2 laser and topical steroids. For the second group the interventional components of combinations include Narrowband Ultraviolet B, Microneedling and topical steroids. Interventional combinations in 4 modes will be allocated randomly to the four resistant vitiligo Patches. The considered time for intervention is 4 months. Patients' follow-up begins from the beginning of interventions and lasts 6 months. The total duration of the study considering patients' recruitment is estimated 30 months. Primary expected outcomes of the study are repigmentation and reducing the size of patches and probably the occurrence of complications such as redness and irritation as the results of interventions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111630918N1**

Registration date: **2017-02-06, 1395/11/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-06, 1395/11/18

Registrant information

Name

Mohammadreza Rahbar

Name of organization / entity

No 4, Skin and Stem Cell Research Center- Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 212122201710

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mrzrahbar@gmail.com

Recruitment status

Recruitment complete

Funding source

The funds from Skin and Stem Cell Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2017-02-11, 1395/11/23

Expected recruitment end date

2017-04-18, 1396/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing and assessment the effects of Fractional CO2 laserr and Microneedling combined with narrowband ultraviolet B and topical steroid for treating non-segmental vitiligo in resistant localizations

Public title

Comparing the effects of Laser and Microneedling combined with phototherapy and topical steroid for treating vitiligo in resistant localizations of body

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: non-segmental vitiligo patients (generalized vitiligo) referred to the skin and stem cell research center of Tehran University of Medical Sciences; Resistant to NUVB (had no or complete response to NBUVB after a period of 3 to 6 months) or the patches on bony prominences or end extremities which are usually resistant to NBUVB; Age more than 18 and less than 80 years old; Have patches on the extremities or trunk at least at 4 points greater than 4 cm2; The patient is willing and able to give informed written consent, Exclusion criteria: Skin type 1; History of photosensitivity; HSV recurrent skin infections; Hypertrophic scars in the patches; Colloid; Heart failure; Patients who are pregnant or lactating; Patients who are not able to understand the process that will take place for them; Patients with melanoma or non-melanoma skin cancer; Patient who has atypical and dysplastic nevus

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of research- Tehran University of Medical Sciences

Street address

The Secretary for Ethic Committee- Research and Technology Issue Management- Floor 6th- Tehran University of Medical Sciences Headquarter- Cross Ghods Ave and Bolvar Keshavarz- Tehran- Iran

City

Tehran

Postal code

Approval date

2016-06-19, 1395/03/30

Ethics committee reference number

IR.TUMS.VCR.REC.1395.152

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

vITILIGO

Primary outcomes

1

Description

Scale of pigmentation improvement of lesion(scale of repigmentation)

Timepoint

1 week, 4 week, 2 months, 4 months and 6 months after start of treatment

Method of measurement

The scale of repigmentation (increase the amount of pigment in vitiligo patches) will be classified based on percentage of improvement in 4 grades. The ratings are: Scale 0: no repigmentation- Scale 1: Returning pigmentation between 0% to 25% which is mild pigmentation- Scale 2: The return of pigmentation 25% and 50% which is average- Scale 3: Good pigmentation which is between 50% to 75%- Scale 4: the return of pigmentation between 75% and 100% which is considered excellent. Measurements are performed by a physician through examination under a Wood's lamp and photography.

2

Description

Complications due to interventions

Timepoint

1 week, 4 week, 2 months, 4 months and 6 months after start of treatment

Method of measurement

Every kind of local or generalized complication due to intervention which according to the confirm of dermatologist should be recorded in the questionnaire. These complications are usually redness and irritation at the site of intervention.

3

Description
Reducing the size of vitiligo lesions (lesion area)
Timepoint
1 week, 4 week, 2 months, 4 months and 6 months after start of treatment
Method of measurement
The scale of decreasing the area of vitiligo patches based on Vitiligo Area Scoring Index(VASTI) which will be assessed by physician.

Secondary outcomes

1

Description
Patient satisfaction
Timepoint
6 months after intervention
Method of measurement
The patient satisfaction score based on Global Satisfaction Using Likert Score

Intervention groups

1

Description
The second combination of interventions for the second group: 1. NB-UVB with microneedling and topical steroids for one of the vitiligo patches 2. NB-UVB therapy with Microneedling for one of the vitiligo patches 3. NB-UVB therapy with topical steroids for one of the vitiligo patches 4. NB-UVB therapy alone for one of the vitiligo patches For the second interventional group 4 types of single or combined interventions will be allocated randomly on four vitiligo patches. Microneedling will be done 8 times, with the intervals of 2 weeks during a period of 4 months using MT.DERM GmbH, Gustav-Krone-Str.3 made by Germany. The depth of penetration for this procedure will be set on 1 mm the same as laser therapy for the first group. NB-UVB (phototherapy) UV 7001K will be done after 5 days after the first microneedling. The starting dose is 50 mj in square centimeters. It will be done twice a week for 8 weeks. Raising the therapeutic dose of phototherapy is 15 percent in each time. After starting the second half of intervention (start of 8th week) phototherapy will be done again in the same afore-mentioned protocol. Topical ointment Clobetasol .05% will be applied three times daily for 3 weeks and one week interruption. It begins again after 4th week and will be continued to 4 months after initiation of interventions. Based on above, the interventions will be accomplished for a period of 4 months. One week, 4 weeks, 2 months, 4 months and six months monitoring of different outcomes will be done after the start of interventions.
Category
Treatment - Devices

2

Description
The first combination of interventions for the first group: 1. NB-UVB therapy with CO2 Fractional Laser and topical steroids for one of the vitiligo patches 2. NB-UVB therapy with CO2 Fractional Laser for one of the vitiligo patches 3. NB-UVB therapy with topical steroids for one of the vitiligo patches 4. NB-UVB therapy alone for one of the vitiligo patches For the first interventional group 4 types of single or combined interventions will be allocated randomly on four vitiligo patches. Two sessions of fractional CO2 laser therapy will be accomplished at the beginning and after 8 weeks using 10 600 nm eCO2 laser (Lutronic Corporation, Goyang, Korea). The energy pulse will be set on 100 Joules with 150 points per cm2 density in static state. NB-UVB (phototherapy) UV 7001K will be done after 5 days after each laser treatment. The starting dose is 50 mj in square centimeters. It will be done twice a week for 8 weeks. Raising the therapeutic dose of phototherapy is 15 percent per in each time. After the second laser treatment, phototherapy will be done again in the same afore-mentioned protocol. Topical ointment Clobetasol .05% will be applied three times daily for 3 weeks and one week interruption. It begins again after 4th week and will be continued to 4 months after initiation of interventions. Based on above the interventions will be accomplished for a period of 4 months. One week, 4 weeks, 2 months, 4 months and six months monitoring of different outcomes will be done after the start of interventions.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology clinic in Skin and Stem Cell Research Center of Tehran University of Medical Sciences
Full name of responsible person
Dr Mohammadreza Rahbar- PhD by research student
Street address
No 4- Maryam Alley- Kamranieh Ave- Sadr Highway- Tehran- Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Skin and Stem Cell Research Center of Tehran University of Medical Sciences
Full name of responsible person
Dr Hamidreza Fattah- Executive Manager for the Skin and Stem Cell Research Center
Street address

No 4- Maryam Alley- Kamranieh Ave- Sadr Highway- Tehran- Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Skin and Stem Cell Research Center of Tehran University of Medical Sciences

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 and Stem Cell research Center of Tehran University of Medical Sciences

Full name of responsible person

Dr Parvin Mansouri

Position

Dermatology specialist- Professor of Tehran University of Medical Sciences- Deputy for Research in S

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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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