

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assay of the CO2 fractional laser and micro needling plus hair follicle transplantation in the treatment of refractory and stable vitiligo.

Protocol summary

Summary

This study aims to assay the effectiveness of Fractional CO2 Laser and Microneedling, each in combination with Narrowband Ultraviolet B Phototherapy for treatment of generalized vitiligo in resistant localizations. Inclusion criteria included: All patients were dermatologically diagnosed with refractory, palmar-plantar vitiligo and exclusion criteria included: hypersensitivity to laser and hair transplantation materials. The study population is 20 patients (Interventional group) and without control group. Components of combinations are Narrowband Ultraviolet B, fractional CO2 laser or Microneedling. 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: **IRCT2017032530808N3**

Registration date: **2017-04-24, 1396/02/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-24, 1396/02/04

Registrant information

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Name of organization / entity

Jahrom University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Jahrom university of medical sciences

Expected recruitment start date

2016-01-13, 1394/10/23

Expected recruitment end date

2016-12-23, 1395/10/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assay of the CO2 fractional laser and micro needling plus hair follicle transplantation in the treatment of refractory and stable vitiligo.

Public title

The effects of Laser and Microneedling combined with phototherapy for treating vitiligo in resistant of hair skin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: All patients were dermatologically diagnosed with refractory, palmar-plantar vitiligo. Exclusion criteria included: hypersensitivity to laser and hair transplantation materials

Age

From **12 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 20

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 jahrom University of Medical Sciences

Street address

Motahari Street, Jahrom University of Medical Sciences, Jahrom, Fars, Iran

City

Jahrom

Postal code

Approval date

2015-07-09, 1394/04/18

Ethics committee reference number

IR.JUMS.REC.1394.184

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

in Three month ,each month once after intervention

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.

Secondary outcomes

1

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.

Intervention groups

1

Description

Comparable vitiliginous lesions were selected from both sides of the body. On Day 0, heavily pigmented follicular grafts were harvested from the scalp by follicular unit extraction and transplanted in a 1-cm grid pattern throughout the selected lesions. At Day 30±4 and Day 60±4, left-sided lesions received single treatments with fractional CO2 laser, MX-7000 (10,600 nm, 100 MJ pulse energy and 200 spots/cm³ in static mode) (Daeshin Enterprise Corporation, Seoul, Korea). Right-sided lesions received 1.5-2 mm needle length-assisted microneedling until pinpoint bleeding was achieved. On Day 30±4 and Day 60±4, silver sulfadiazine ointment was applied to treated skin, twice daily, for 5 days without occlusion. On Day 41±2, right and left-sided lesional skin received NB-UVB phototherapy (dermalight 1,000/1,000 L, 800 W, Power supply: 230 V/50 Hz; Dr. Honle medizintechnik, GmbH, Germany) three times a week until Day 60±4; phototherapy was restarted on day 71±2. The phototherapeutic dose was increased by 15% at each treatment interval and was completed by Day 100±4 (for a total of 12 weeks of treatment). Clobetasol 45% solution was applied twice daily throughout the phototherapy phase of the study. The diameter of repigmentation around each graft was measured with appropriately calibrated calipers at baseline, Day 30±4, Day 60±4 and Day 100±4.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic in Skin of Dr Feili

Full name of responsible person

Street address

City

Jahrom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Jahrom University of Medical Sciences

Full name of responsible person

Kavoos Solhjo

Street address

Motahari Street, Jahrom University of Medical Sciences, Jahrom, Fars, Iran Jahrom

City

Jahrom

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, Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

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Position

clerk

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