

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison of the efficacy of topical latanoprost and fractional CO2 laser with placebo and fractional CO2 laser in treatment of vitiligo with acral involvement, phototherapy unit, Faghihi hospital, Shiraz, 2020

#### Protocol summary

##### Study aim

Comparison the effect of fractional CO2 laser and topical latanoprost with laser and placebo in acral vitiligo in patients on phototherapy

##### Design

In this double-blind control trial, vitiligo patients with bilateral acral lesions that are on phototherapy, randomly used latanoprost eye drop or placebo on each side after CO2 fractional laser. Laser will be done every two weeks and drug and placebo apply by patient twice daily for one week post laser. Drug and placebo are coded in same boxes and uncode at the end of the study. Every sessions before laser, photographs were taken and side effects recorded. VASI score and VAS are used for assessment.

##### Settings and conduct

At Emam Reza clinic, dermatology unit, 24 acral vitiligo patients were included in this double blind control trial study, by treatment with latanoprost and placebo and fractional CO2 laser.

##### Participants/Inclusion and exclusion criteria

Patients have age 14 or more with symmetrical vitiligo patches, receiving phototherapy (NB-UVB, PUVA). Patients discontinued all their systemic or topical vitiligo treatments for one month. Patients with a history of allergy to prostaglandins, pregnant or breast-feeding women, uncontrolled systemic disorders and history of keloids were excluded.

##### Intervention groups

In case group, patients apply latanoprost 0.005% eye drop after fractional laser and control group apply placebo after laser.

##### Main outcome variables

Qualitative assessment with VASI score and VAS

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120909010795N4**

Registration date: **2020-12-08, 1399/09/18**

Registration timing: **retrospective**

Last update: **2020-12-08, 1399/09/18**

Update count: **0**

##### Registration date

2020-12-08, 1399/09/18

##### Registrant information

##### Name

Nasrin Saki

##### Name of organization / entity

Dermatology Department, Shiraz university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 19049

##### Email address

sakina@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2020-11-21, 1399/09/01

##### Actual recruitment start date

2020-07-22, 1399/05/01

##### Actual recruitment end date

2020-11-21, 1399/09/01

**Trial completion date**

2020-11-21, 1399/09/01

**Scientific title**

Comparison of the efficacy of topical latanoprost and fractional CO2 laser with placebo and fractional CO2 laser in treatment of vitiligo with acral involvement, phototherapy unit, Faghihi hospital, Shiraz, 2020

**Public title**

Fractional CO2 laser and topical latanoprost in acral vitiligo

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age more than 14 Acral vitiligo patche(s) resistant to phototherap Discontinue all systemic and topical treatments for 1 month At least 1 lesion in each side with size of 2\*2 to 8\*8 cm

**Exclusion criteria:**

Poor compliance Allergy to latanoprost Pregnant or breast-feeding women Age before 14 Uncontrolled systemic disorders that interfere with wound healing process Autoimmune disorders History of allergy to any drug Any psychological disorders Unilateral lesions Active infection at laser site History of keloids

**Age**

From **14 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **2**

Bilateral symmetrical acrl patches

Actual sample size reached: **24**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Bilateral symmetrical acrl patches

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A lesion in each side selected and randomly (blocked randomization) assigned to receive latanoprost or placebo: one side received fractional CO2 laser followed 0.005% solution of latanoprost, and the other side fractional CO2 laser and placebo.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this double-blind study, patients and physicion are blind. Drug and placebo have codes that decode at the

end of the study.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Faghihi hospital, Zand Blvd.

**City**

Shiraz

**Province**

Fars

**Postal code**

71348846114

**Approval date**

2019-07-29, 1398/05/07

**Ethics committee reference number**

IR.SUMS.MED.REC.1398.312

**2****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

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Fars

**Postal code**

71348846114

**Approval date**

2019-07-29, 1398/05/07

**Ethics committee reference number**

IR.SUMS.MED.REC.1398.312

**Health conditions studied****1****Description of health condition studied**

Vitiligo

**ICD-10 code**

L80

**ICD-10 code description**

Vitiligo

## Primary outcomes

### 1

#### Description

Skin pigmentation

#### Timepoint

At the beginning of study and after 5 sessions of laser therapy, at the end of the study

#### Method of measurement

Qualitative assessment with VASI score and VAS

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 24 vitiligo patients with bilateral symmetrical lesions, on phototherapy, on one side took CO2 fractional laser (Microxel, MX7000, Korea) with energy level of 22 to 24 mj, repeat time of 500ms, for 2 to 3 passes, every two weeks. In the first week post laser, they apply latanoprost eye drop 0.005% solution (Sina daruo), two times a day at laser site.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: 24 vitiligo patients with bilateral symmetrical lesions, on phototherapy, on one side took CO2 fractional laser (Microxel, MX7000, Korea) with energy level of 22 to 24 mj, repeat time of 500ms, for 2 to 3 passes, every two weeks. In the first week post laser, they apply placebo two times a day at laser site.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faghihi hospital

##### Full name of responsible person

Nasrin Saki

##### Street address

Faghihi hospital, Dermatology department, Zand Blvd.

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7134846114

##### Phone

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sakina@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Younes Ghasemi

##### Street address

7th floor, Central Shiraz University of Medical science building, Zand Blvd.

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##### Fax

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##### Email

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#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Fatemeh Rahmanian

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dermatology

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Latest degree**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Data about main result of the patient's treatment can be shared.

### When the data will become available and for how long

3 months after publication.

### To whom data/document is available

Researchers of academic centers.

### Under which criteria data/document could be used

For the same clinical researches.

### From where data/document is obtainable

Email to the researcher.

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

By email or call the researcher, data of this research will be available in about one month.

### Comments