Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, photographes 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 patiantes 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

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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

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Postal code
71348846114

Approval date
2019-07-29, 1398/05/07

Ethics committee reference number
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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% soution (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
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Sponsors / Funding sources

1

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Name of organization / entity
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Full name of responsible person
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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
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Person responsible for updating data

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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 publishment.

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