

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of the efficacy of fractional co2 laser alone and in combination with topical latanoprost drop in repigmentation of hypopigmented scars

Protocol summary

Summary

The goal of this study is to compare between efficacy of fractional co2 laser alone and in combination with topical latanoprost drop in repigmentation of hypopigmented scars. This study is a double blind(both patients and practitioners were blind to the trial), randomized, placebo-controlled, clinical trial. This study contain two group that 14 patients present in each group(in total 28 patients). In either group, 6 session of laser treatment with one month interval were performed. in first group, in addition to laser treatment, topical latanoprost drop is used twice daily, and in second group distill water drop (in package identical to latanoprost) is used twice daily as placebo. Inclusion criteria include age between 15 to 50 years, skin phototype 1 to 4, negative history of systemic retinoid therapy(isotretinoin and acitretin) in recent 6 month. Exclusion criteria include history of hypersensitivity reaction to topical latanoprost, pregnancy, lactation. The patients were divided in two group, using table of randomization. Prior to treatment, all patients were photographed. 3 month after last session of laser treatment the patients were assessed by a dermatologist who was not aware of method of treatment. The assessment was done by using of quartile scale (0-25%,25-50%,50-75%,75-100%), then the results of two trial groups were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013123016002N1**

Registration date: **2014-03-19, 1392/12/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-19, 1392/12/28

Registrant information

Name

Reza Rezaei

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-04-28, 1392/02/08

Expected recruitment end date

2014-01-26, 1392/11/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of fractional co2 laser alone and in combination with topical latanoprost drop in repigmentation of hypopigmented scars

Public title

Treatment of hypopigmented scar (ulcer, burning and etc) with laser and latanoprost drop

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: age between 15 to 50 years, skin phototype 1 to 4, negative history of systemic retinoid therapy (isotretinoin and acitretin) in recent 6 month.
 Exclusion criteria: history of hypersensitivity reaction to topical latanoprost, pregnancy, lactation

Age
 From **15 years** old to **50 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **28**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Isfahan University of Medical Sciences

Street address
 Isfahan University of Medical Sciences, Hezar Jerib Aven, Isfahan

City
 Isfahan

Postal code

Approval date
 2013-01-23, 1391/11/04

Ethics committee reference number
 392019

Health conditions studied

1

Description of health condition studied
 Hypopigmented scar

ICD-10 code
 L90.5

ICD-10 code description
 Scar NOS

Primary outcomes

1

Description
 Repigmentation of hypopigmented scar

Timepoint
 baseline, monthly for 6 months, 3month after last session of laser treatment

Method of measurement
 Physician observation and scoring according to quartile scale (0-25%,25-50%,50-75%,75-100%)

Secondary outcomes

1

Description
 side effect of latanoprost drop include hypersensitivity reaction

Timepoint
 monthly

Method of measurement
 clinical evaluation

2

Description
 side effects of laser include erythema, pain and burning sensation

Timepoint
 monthly

Method of measurement
 clinical evaluation

Intervention groups

1

Description
 6 session of fractional co2 laser treatment with one month interval were done (with fluence of 400mj/cm2). In addition to laser therapy, distill water drop was applied twice daily as placebo.

Category
 Treatment - Other

2

Description
 6 session of fractional co2 laser treatment with one month interval were done (with fluence of 400mj/cm2). In addition to laser therapy, topical latanoprost drop was applied twice daily.

Category
 Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra hospital, dermatology clinic

Full name of responsible person

Dr. Reza Rezaei

Street address

Dermatology group, Al-zahra hospital, Soffeh Blvd,
Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of
Medical Sciences

Full name of responsible person

Dr. Ebrahim Esfandiari, Vice chancellor for research,
Isfahan University of Medical Sciences

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Isfahan University of Medical Sciences, Hezar Jerib
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Isfahan

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, Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Reza Rezaei

Position

Resident of dermatology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

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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