Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the efficacy of topical tranexamic acid 5% gel with and without fractional CO laser therapy in treatment of melasma

Protocol summary

Summary

The study is designed to compare the additive efficacy of fractional CO2 laser with topical tranexamic acid gel in the treatment of melasma. The study is a randomized, single-blin, unicenter, clinical trial. Inclusion criteria include patients with epidermal and mixed melasma and diseased for at least 6 months. Exclusion criteria include dermal type melasma, oral contraceptive pill consumption since 3 months before enrolement in the study, topical or oral corticosteroid consumption, other pigmentation disorders,history of endocrinopaty disorders, pregnancy, lactation, topical depigmenting medication application in the recent 1 month, oral retinoids or oral and injectable tranexamic acid consumption in the recent 6 months. The patients are selected by convenient sampling from tinea versicolor patients referred to dermatology clinic of Faghihi hospital in Shiraz and 25 patients are enrolled in the study. The patients receive two treatments in both sides of their face by block randomization. In the intervention side which is determined by block randomization, once monthly fractional CO2 laser is done besides twice daily topical application of tranexamic acid gel and in the control side, only topical tranexamic acid gel is applied twice daily. Primary outcome measure is melanin content measured by Dermacatch instrument and secondary outcome measures are modified Melasma Area and Severity Index (mMASI), investigator global scale and patient global scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080716557N3**
Registration date: **2017-08-13, 1396/05/22**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-08-13, 1396/05/22

Registrant information

Name
Mozhdeh Sepaskhah
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Research council of Shiraz University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of topical tranexamic acid 5% gel with and without fractional CO laser therapy in treatment of melasma

Public title

Effect of fractional CO2 laser and Tranexamic acid gel in the treatment of melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with epidermal and mixed melasma; diseased for at least 6 months Exclusion criteria: Dermal type melasma; Oral contraceptive pill consumption since 3 months before enrolement in the study; Topical or oral corticosteroid consumption; Other pigmentation disorders; History of endocrinopaty disorders; Pregnancy; Lactation; Topical depigmenting medication application in the recent 1 month; Oral retinoids or oral and injectable tranexamic acid consumption in the recent 6 months

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand St., Shiraz. Iran

City

Shiraz

Postal code

Approval date

2017-06-14, 1396/03/24

Ethics committee reference number

IR.SUMS.MED.REC.1396.48

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Melanin content

Timepoint

months 0, 1, 2, 3

Method of measurement

A number measured by Dermacatch

Secondary outcomes

1

Description

modified Melasma Area and Severity Index (mMASI)

Timepoint

months 0, 1, 2, 3

Method of measurement

Scoring of color and extent of lesions and calculation based on the formula

2

Description

Investigator global scale

Timepoint

months 0, 1, 2, 3

Method of measurement

Investigator's assessment of global severity of the lesion

3

Description

Patient global scale

Timepoint

months 0, 1, 2, 3

Method of measurement

Patient's assessment of global severity of the lesion

Intervention groups

1

Description

Intervention side: Once monthly fractional CO2 laser (DSE, South Korea), 169 dots per pulse, energy 12mJ, 1-2 pass for 3 sessions is done besides twice daily topical application of tranexamic acid 5% gel for 3 months

Category

Treatment - Surgery

2

Description
Control side: Only topical tranexamic acid 5% gel is applied twice daily for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology clinic, Shahid Faghihi hospital
Full name of responsible person
Leila sadat Khamesi
Street address
Dermatology clinic, Faghihi hospital, Zand St., Shiraz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Council of Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyed Basir Hashemi
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Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran
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Grant name
Grant code / Reference number
93-01-01-8716
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Council of Shiraz 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
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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