Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy and safety of topical Hydroquinon with and without using fractional Erbium YAG LASER in treatment of melasma

Protocol summary

Study aim

Comparison of efficacy and safety of topical Hydroquinon with and without using fractional Erbium YAG LASER

Design

A concealed, randomized, double blind inter_patient placebo controlled clinical trial(phase 3) with a parallel group designed of 27 patients. Block randomization will be done.

Settings and conduct

Twenty seven patients eligible for criteria referred to the Razi hospital will be included in the study.Erbium YAG LASER will be used on an area with diameter of 2*2 cm on the frontal area, then sunscreen and Hydroquinon 4% will be used on both sides of face, for 1 month. After 1 month patients will be visited.If there is no side effect LASER (Erbium YAG) therapy will be started randomly on one side of the face. Patients will receive treatment every 4 weeks for 3 sessions, then they will be followed up for 3 month after the last session and topical treatment will be continued during this period. If side effect such as permanent erythema, scar and post inflammatory hyper-pigmentation occurs treatment will be discontinued.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-65 years; symmetrical Melasma in both half of the face; patients' satisfaction; skin type 1-3 Exclusion criteria: use of topical and oral Retinoid, topical steroid, Alpha Hydroxy acids and other drugs effect on pigmentation in past 4 weeks; use of Oral Contraceptive Pills; chemical peeling, Microdermabrasion, Dermabrasin or laser during past 3 months; history of past sensitivity to Hydroquinon; pregnancy or lactation

Intervention groups

Intervention group: topical Hydroquinon4% cream once a day with fractional Erbium YAG LASER monthly Control group: topical Hydroquinon4% cream once a day

Main outcome variables

Pigmentation, topical adverse effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181201041812N1**
Registration date: **2019-09-25, 1398/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-25, 1398/07/03**
Update count: **0**

Registration date

2019-09-25, 1398/07/03

Registrant information

Name

Fatemeh Nasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5560 9951

Email address

drfatemehnasiri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of topical Hydroquinon with and without using fractional Erbium YAG LASER in treatment of melasma

Public title
The efficacy of topical Hydroquinon with and without using Erbium YAG LASER in treatment of melasma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Symmetrical melasma in both half of the face Patients satisfaction Skin type 1-3
Exclusion criteria:
Pregnancy or lactation Use of alpha hydroxy acids and other drugs effect on pigmentation during past 4 weeks Use of topical and oral retinoid Use of topical steroid Use of Oral Contraceptive Pills Chemical peeling ,microderm abrasion, derm abrasion or LASER during past 3 months History of keloid History of past sensitivity to hydroquinon History of thyroid dysfunction LASER therapy in past 3 months
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **27**
More than 1 sample in each individual
Number of samples in each individual: **2**
In every patient face will be divided to right and left side. Hydroquinon in one side and laser plus Hydroquinon in the other side will be applied.
Randomization (investigator's opinion)
Randomized
Randomization description
With block randomization we use laser in left or right side of face
Blinding (investigator's opinion)
Not 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 Tehran University of Medical Science
Street address
Room No. 105, 5th floor, Central building,Tehran University of Medical Science , Ghods avenue, Keshvarz boulevard, Tehran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2018-06-11, 1397/03/21
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.185

Health conditions studied

1

Description of health condition studied
Melasma
ICD-10 code
L81.1
ICD-10 code description
Chloasma

Primary outcomes

1

Description
Pigmentation
Timepoint
Before intervention,at the end of intervention,1 mouth and 3 mouths after end of intervention
Method of measurement
Modified Melasma Area and Severity Index(mMASI) score,digital photography,patient satisfaction(questionnaire),physician assessment

2

Description
Topical adverse effects
Timepoint
Every month in intervention period and the end of intervention
Method of measurement
Questionnaire and observation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Topical Hydroquinon4% as kligman formula, every night with fractional Erbium YAG LASER

Category
Treatment - Drugs

2

Description
Control group: Hydroquinon cream 4% as kligman formula nightly
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Fatemeh Nasiri
Street address
Razi Hospital, Vahdat eslami Square, Vahdat Eslami Street
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Web page address
http://razihos.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Nasiri
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person
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Resident
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
IPD collected from the primary outcome measure only
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used
Scientific research
From where data/document is obtainable
Fatemeh Nasiri drfatemehnasiri@yahoo.com
What processes are involved for a request to access data/document
The application is sent by official university email which should contain the recipient's information and the purpose of his/her request. After having verified the accuracy of the information, files would be sent.
Comments