

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Effectiveness of Hydroquinone 4% and Fractional CO2 Laser combination vs. Hydroquinone 4% Monotherapy in women from the age range of 20-50 years with melasma.

Protocol summary

Study aim

To evaluate the efficacy of fractional CO2 laser in combination with topical therapy in melasma treatment.

Design

A parallel group, single-blinded, blocked randomization clinical trial, design of 40 patients, enrolled between February 2015 and March 2016, and followed at three-week intervals and one and three months after the last laser session

Settings and conduct

Each side of the face was randomly allotted to either topical hydroquinone 4% or combination of topical hydroquinone 4% and Fractional CO2 laser. The patients received three sessions of laser therapy at 3-week intervals. They were asked to use hydroquinone 4% on both sides for 3 months after the last laser session during follow-up. The clinical improvement was measured by an impartial blinded physician.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female, age range of 20-50 years, Fitzpatrick skin types II-V, bilateral melasma. Exclusion criteria: history of receiving laser therapy and topical therapeutic agents in the previous three months, Isotretinoin in the past six months, OCP, other bleaching creams, phenytoin, phototoxic and photoallergic drugs, pregnancy and lactating.

Intervention groups

For each patient, one cheek is considered as the control (Hydroquinone group) and the other cheek as the experiment (laser and Hydroquinone group).

Main outcome variables

Darkness of hyperpigmentations. Homogeneity of hyperpigmentations response to treatment due to the percentage improvement in the lesions. Patient's satisfaction with the treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171222037987N1**

Registration date: **2018-06-30, 1397/04/09**

Registration timing: **retrospective**

Last update: **2018-06-30, 1397/04/09**

Update count: **0**

Registration date

2018-06-30, 1397/04/09

Registrant information

Name

Farahnaz Fatemi Naeini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 4781

Email address

fatemi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-02-04, 1393/11/15

Expected recruitment end date

2015-10-06, 1394/07/14

Actual recruitment start date

2015-02-04, 1393/11/15

Actual recruitment end date

2016-03-10, 1394/12/20

Trial completion date

empty

Scientific title

Comparison of Effectiveness of Hydroquinone 4% and Fractional CO2 Laser combination vs. Hydroquinone 4% Monotherapy in women from the age range of 20-50 years with melasma.

Public title

Combination of Hydroquinone and Fractional CO2 Laser vs. Hydroquinone Monotherapy in Melasma Treatment: A Randomized Split-face Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female patients Age range of 20-50 years Fitzpatrick skin types II-V Bilateral melasma on cheeks

Exclusion criteria:

History of receiving laser therapy and topical therapeutic agents in the previous three months History of receiving Isotretinoin in the past six months History of receiving OCP, other bleaching creams, phenytoin, phototoxic and photoallergic drugs Pregnancy Lactating

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

More than 1 sample in each individual

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

for each patient one cheek is considered as the control and the other cheek as the experiment

Actual sample size reached: **37**

More than 1 sample in each individual

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

for each patient one cheek was considered as the control and the other cheek as the experiment

Randomization (investigator's opinion)

Randomized

Randomization description

For each patient one cheek was considered as the control (Hydroquinone group) and the other cheek as the experiment (laser and Hydroquinone group) according to blocked randomization which was generated by a third independent person who was not involved in the study. Participants were randomized in to group A (right cheek as the experiment) and group B (left cheek as the experiment) within then blocks of four each. Randomly generated treatment allocations were concealed in the forty envelopes which were sequentially numbered and opened only after each patient was consented to enter the trial.

Blinding (investigator's opinion)

Single blinded

Blinding description

the main investigators, data analysors and out come assessors were blinded. Severity of the melasma lesions was assessed objectively by the main investigator who was blinded to the treatment being given on each side and consultant dermatologist who was blinded to the type of treatments applied and aim of the study. Furthermore, response to treatment was evaluated subjectively by the main investigator and another consultant dermatologist who was blinded to the treatment being given on each side and the aim of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical sciences, Hezar Jerib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2013-01-20, 1391/11/01

Ethics committee reference number

391095

Health conditions studied

1

Description of health condition studied

melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Severity of the melasma lesions was assessed objectively based on Darkness (D) and Homogeneity (H) using a 7-point scale (0-6).

Timepoint

The darkness and homogeneity scores were obtained in the first visit and the 3 laser sessions at three-week intervals and the follow-up sessions at 1 and 3 months after the last laser session.

Method of measurement

darkness and homogeneity : 7-point scale(compare with the sample) patient's satisfaction with the treatment :visual analogue scale (VAS) by scoring between 0 and 10 response to treatment : physician global assessment

Secondary outcomes**1****Description**

patient's satisfaction with the treatment.

Timepoint

3 months after the last laser session.

Method of measurement

visual analogue scale (VAS) by scoring between 0 and 10.

Intervention groups**1****Description**

Intervention group: for each patient one side of the face was randomly allotted to topical hydroquinone 4% and Fractional CO2 laser (combination therapy group). Patients received three sessions of laser therapy at 3-week intervals with the Dios instrument. (Laser fluence of 5 J/cm2, Dot cycle of 6 and Pixel pitch of 2).

Category

Treatment - Drugs

2**Description**

Control group: for each patient one side of the face was randomly allotted to topical hydroquinone 4% (monotherapy group). Hydroquinone 4% was applied during the study and maintained for 3 months after the last laser session.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Farahnaz Fatemi Naeini

Street address

Department of Dermatology, Alzahra Hospital , Soffeh Blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2087

Email

fatemi@med.mui.ac.ir

Web page address

<http://med.mui.ac.ir/?q=post/post>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash

Street address

4th building, Isfahan University of Medical Sciences, Hezar Jerib Ave, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3792 2252

Email

research@mui.ac.ir

Web page address

<http://research.mui.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Farahnaz Fatemi Naeini

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Department of Dermatology, Alzahra Hospital, Soffe
Blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2087

Email

fatemi@med.mui.ac.ir

Web page address

<http://med.mui.ac.ir/?q=post/post>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Farahnaz Fatemi Naeini

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Department of Dermatology, Alzahra Hospital, Soffe
Blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2087

Email

fatemi@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Farahnaz Fatemi Naeini

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Department of Dermatology, Alzahra Hospital, Soffe
Blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2087

Email

fatemi@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available