

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

A comparative study between conventional and liposomal topical hydroquinone 4 % on melasma treatment

Protocol summary

Summary

Melasma is a common acquired hyperpigmentation seen mainly in women and occurs on the face. This study aims to compare the effects of liposomal and conventional hydroquinone on patients with Melasma. Patients with age over 18 years old are included in the study and asked to fill out written consent forms. Then patients who have exclusion criteria like pregnancy and breastfeeding, drug use, infectious skin diseases, not having regular follow ups and etc will be excluded from study. A double blind clinical trial is conducted among 20 women for 12 weeks. Participants are asked to use liposomal hydroquinone on one side of face and topical hydroquinone on the other side of face once a day and sunblock every 3 hours a day. Skin pigmentation is then measured using MASI (Melasma area severity index) during each visit separately for each side and 1 month after last visit. Then the data obtained from patients file are statistically analyzed using SPSS software, paired samples T test and repeated measured ANOVA.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405283862N13**

Registration date: **2017-10-09, 1396/07/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-09, 1396/07/17

Registrant information

Name

Farahzad Jababri Azad

Name of organization / entity

Mashahd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1843 6626

Email address

banihashemim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2013-12-02, 1392/09/11

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study between conventional and liposomal topical hydroquinone 4 % on melasma treatment

Public title

Comparison of the effect of conventional and liposomal topical hydroquinone 4 % on melasma treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Clinical Melasma; age over 18.

Exclusion criteria: Pregnancy or breastfeeding; Infectious skin diseases; Simultaneous important medical conditions; Drug use (OCP, anticonvulsants, recent hormone therapy and Corticosteroids); Patients who used bleaching drug treatment in the last 4 months; Patients who had laser and IPL operations in the last 6 months;

Patients who did not have follow ups at regular appointed times; In case of side effects.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double 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 Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Postal code

Approval date

2014-02-08, 1392/11/19

Ethics committee reference number

IR.MUMS.REC.1392.806

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

disease severity

Timepoint

once a month and one month after last visit

Method of measurement

Melasma area severity index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: liposomal hydroquinone %4 was prescribed for one side of face once a day and also use of sunblock every 3 hours daily for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: conventional topical hydroquinone %4 was prescribed for one side of face once a day and also use of sunblock every 3 hours daily for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Dr Faeze Golnouri

Street address

Ahmad Abad Avenue, Ghaem Hospital

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

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 of Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr Faeze Golnouri
Position
Dermatology Assistant
Other areas of specialty/work
Street address
Ghaem Hospital, Ahmad Abad Avenue
City
Mashhad
Postal code
Phone
+98 51 3801 2493
Fax
Email
golnourif92@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mahnaz Banihashemi
Position
Professor of dermatology

Other areas of specialty/work
Street address
Ghaem Hospital, Ahmad Abad Avenue
City
Mashhad
Postal code
Phone
00285138012493
Fax
Email
banihashemim@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Akram Momenzadeh
Position
Bachelor of Biology
Other areas of specialty/work
Street address
Cutaneous Leishmaniasis Research Center, Mashhad University of Medical Sciences
City
Mashhad
Postal code
Phone
00
Fax
Email
src@mums.ac.ir
Web page address

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