

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

A comparative study of hydroquinone cream 4% and methimasole cream 5% in melasma patients

Protocol summary

Summary

A randomized double-blind controlled trial was conducted to compare the effect of topical methimazole with hydroquinone. The study participants comprised 50 women 20-50 years old with epidermal type of melasma who had taken no medication within 3 months before the study and referred to the outpatient dermatology clinics of Shohada-e Tajrish Hospital and Loghman hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran during 2015. Patients were randomly divided to two groups: HQ group and MMI group. All patients received treatments for 8 weeks and patients were advised to use only sunscreen for 4 weeks after the end of the treatment as well. Melasma status was assessed at the end of 4 weeks, 8 weeks and 12 weeks. Both the patients and outcome assessors were blinded to the type of treatment received. The creams were labeled A & B by pharmacist and used in a double-blind study by the research team. The codes were disclosed by the pharmacist at the end of the trial. Outcome of the study as pigmentation reduction was assessed through subjective and objective methods which analyzed and reported: 1. Melasma Area and Severity Index (MASI) 2. Patient satisfaction scaled 3. Physician Evaluation by two dermatologists which were blinded to therapies (they assessed digital photographs taken at baseline visit, intermediate visit at week 4 and 8, and subsequent visit at week 12 and then ranked efficacies. Safety assessment was based on the adverse effects as mentioned by the patient and evaluated by the investigator.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041727445N1**

Registration date: **2016-04-30, 1395/02/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-30, 1395/02/11

Registrant information

Name

Elham Olamaei

Name of organization / entity

Skin Research center

Country

Iran (Islamic Republic of)

Phone

+98 22741507

Email address

dr.olamaei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2015-03-11, 1393/12/20

Expected recruitment end date

2015-11-20, 1394/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of hydroquinone cream 4% and methimasole cream 5% in melasma patients

Public title

Compare the effect of methimazole and hydroquinone cream in the treatment of melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:All the people in the age range of 50-20 years and all topical treatments for at least one month prior to study entry and are cut by a dermatologist examination with Wood's light examination (Wood) disease of epidermal melasma approved exclusion criteria and do not have;All people have informed consent to participate in the scheme. Exclusion criteria:Pregnancy and lactation;There Type of melasma 3Use of any treatment for melasma in the last month;Use of oral contraceptives and hormone therapy and medication have any phototoxic;Past medical history of any thyroid disorders in patients

Age

From **20 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)

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 Shahid Beheshti University of Medical Sciences

Street address

Arab street next Shahid Ayatollah Taleghani Hospital, Highway Chamran Street Yemen, Tehran

City

Tehran

Postal code

1985717443

Approval date

2015-03-11, 1393/12/20

Ethics committee reference number

Fourteenth meeting of the Committee descendants 93/43

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

L8101

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Efficacy of methimazole 5%cream in severity of melasma with change in colore

Timepoint

Every 4 Weeks

Method of measurement

MASI Score

2

Description

Efficacy of hydroquinone 4%cream in severity of melasma with change in colore

Timepoint

Every 4 weeks

Method of measurement

MASI score

Secondary outcomes

1

Description

Side effects

Timepoint

Every four weeks

Method of measurement

Ask the patient

Intervention groups

1

Description

Control:Use 4% hydroquinone cream every night for 8 weeks

Category

Treatment - Drugs

2

Description

Case:The use of methimazole 5% cream every night for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada-Tajrish Hospital
Full name of responsible person
Street address
City
Tehran

2

Recruitment center

Name of recruitment center
Luqman Hakim Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shahid Beheshti
University Skin Research Center of Medical Sciences
Full name of responsible person
parviz Toosi
Street address
Tehran
City
Tehran

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, Shahid Beheshti University
Skin Research Center 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
Skin Research Centers
Full name of responsible person

Elham Olamaei

Position

Dermatology Resident

Other areas of specialty/work

Street address

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences Skin
Research Centers

Full name of responsible person

Mehdi Gheisari

Position

MD

Other areas of specialty/work

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Other areas of specialty/work

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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