

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of oral finasteride and topical hydroquinone versus placebo and topical hydroquinone in treatment of melasma

Protocol summary

Summary

Introduction: Melasma is an acquired hypermelanosis disease and its treatment is unsatisfactory most of the times. androgenic hormones may have role in pathogenesis of the melasma, and sex-hormone related drugs may have an effect on melasma. So, this study was carried out in order to comparison of efficacy of oral finasteride and topical hydroquinone versus placebo and topical hydroquinone in treatment of melasma in women patients referring to Imam Hospital in Ahwaz. Materials and Methods: This is a randomized double-blind clinical trial study conducted on 30 patients with melasma in 2015. The patients was randomly assigned in to two groups. The first group treated with finasteride 5mg with 4% topical hydroquinone, and the second group treated with placebo plus 4% topical hydroquinone. Demographic and clinical characteristics as well as Melasma Area and Severity Index (MASI) and patient satisfaction will investigated. The collected data will analyzed by the SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031627077N1**

Registration date: **2016-05-28, 1395/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-28, 1395/03/08

Registrant information

Name

Ziba Mehrjuyi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

no funding

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of oral finasteride and topical hydroquinone versus placebo and topical hydroquinone in treatment of melasma

Public title

The effect of finasteride for the treatment of melasma

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patient with melasma and would like to participate in the study exclusion criteria: pregnant and lactating women, patients treated with anti androgenic drugs, oral contraceptive use

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ahwaz Jondishapur University of Medical Sciences

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Jondishapur University of Medical Sciences, Golestan street

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Approval date

2015-05-30, 1394/03/09

Ethics committee reference number

IR.AJUMS.REC.1394.101

Health conditions studied**1****Description of health condition studied**

melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes**1****Description**

melasma

Timepoint

Baseline, the end of the first month, the end of second month, the end of the third month

Method of measurement

By observing the amount of blur, uniformity and percentage of skin involvement in four areas of the forehead, right cheek, left cheek and chin

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

Satisfaction with treatment

Timepoint

end of treatment

Method of measurement

Interviews with patients

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

Control Group: In this group 15 patients received a placebo orally, along with topical hydroquinone 4% daily for three months. Monthly patients response to treatment and side effects are examined

Category

Treatment - Drugs

2**Description**

The intervention group: The group of 15 patients with finasteride 5 mg orally on a daily basis with topical hydroquinone 4% treated on a daily basis for tree month . complications and response to treatment are evaluated monthly

Category

Treatment - Drugs

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

Dermatology department, Ahwaz Imam Khomeini hospital

Full name of responsible person

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

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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

Ahwaz Jondishapur 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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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*