

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Ahwaz Jondishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

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

Mehrjuyi ziba

Street address

Dermatology department, Imam Khomeini hospital, Azadegan street, Ahvaz

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz Jondishapur University of Medical Sciences

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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Postal code

00986155615743

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

Full name of responsible person
Saki nader

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Ahwaz, Golestan street, Ahwaz Jondishapur University

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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

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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