Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the efficacy of oral finastride 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 hormons 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 finastride 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 finastride 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

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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 finastride 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
Street address
Jondishapur University of Medical Sciences, Golestan street
City
Ahwaz
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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
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
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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

Full name of responsible person
Saki nader
Street address
Ahwaz, Golestan street, Ahwaz Jondishapur University
City
Ahwaz
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

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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