

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Clinical trial of topical flutamid on melasma compared with topical hydroquinon

Protocol summary

Summary

Study is a single blind clinical trial. Melasmatic women constitute the study population who shouldn't be pregnant or breastfeeding and not to receive OCPs, spironolactone and phenytoin. Sample size is 40 for each group. Trial group will receive topical flutamid and control group will receive topical hydroquinone. Both groups will use anti-solar treatments. Treatment will last for 4 months and at the end of each month, improvement will be evaluated. Evaluation will be based on mexameter , photography, observations of the physician and patient satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905114310N4**
Registration date: **2010-08-24, 1389/06/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-08-24, 1389/06/02

Registrant information

Name

Hassan Adalatkhah

Name of organization / entity

Ardebil University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 308 6490

Email address

h.edalatkhah@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ardebil medical university

Expected recruitment start date

2008-09-22, 1387/07/01

Expected recruitment end date

2013-12-01, 1392/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of topical flutamid on melasma compared with topical hydroquinon

Public title

Effects of topical flutamid on melasma lesions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Females with melasma 2- Consent to participate Exclusion criteria: 1- Pregnancy 2- Breastfeeding 3- Taking OCP, spironolactone or phenytoin 4- Receiving antipigmentation therapy during the last four months

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description
Blinding (investigator's opinion)

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ardebil medical university

Street address

Deputy of research, Ardebil medical university,
Ardebil

City

Ardebil

Postal code

56189/53141

Approval date

empty

Ethics committee reference number

Number 2

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

Melasma

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Reduction of pigmentation

Timepoint

30 day

Method of measurement

Photography-Mexameter-Clinical examination-Patient
satisfaction

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

Side effects of drugs

Timepoint

One months

Method of measurement

Clinical examination

2**Description**

Patient satisfaction

Timepoint

3 months

Method of measurement

Check list

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

Topical flutamid + antisolar cream for 4 months

Category

Treatment - Drugs

2**Description**

Topical hydroquinon+antisolar cream for 4 months

Category

Treatment - Drugs

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

Dermatology clinic of Babak

Full name of responsible person

Hasan Edalatkhah

Street address

Sarcheshme circus, Ardebil

City

Ardebil

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

Ardebil medical university

Full name of responsible person

Dr Mehrdad Mirzarahimi

Street address

Deputy of research, Ardebil medical university,
Daneshgah street , Ardebil

City

Ardebil

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Ardebil medical university

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**

Deputy of research , Ardebil medical university

Full name of responsible person

Dr Mohsen Arzanlou

PositionManage for research affairs, Research deputy of
Ardabil Medical University, PhD**Other areas of specialty/work****Street address**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ardebil University of medical sciences

Full name of responsible person

Hasan Edalatkhah

Position

MD, Specialty degree in Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

Ardebil medical university

Full name of responsible person

Rasoul Lotfollahzadeh

Position

Research officer

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www.arums.ac.ir

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*