

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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 flutamide 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,
Danezhgah 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

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Emam khomayni hospital, Ardebil

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

Ardebil medical university

Full name of responsible person

Rasoul Lotfollahzadeh

Position

Research officer

Other areas of specialty/work**Street address**

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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

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

Other areas of specialty/work