Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Methimazole 5% cream effectiveness versus Hydroquinone cream 2% in patient with melasma, referred to Dermatology Clinic

Protocol summary

Summary

Objectives: This interventional study as a randomized double blind would be clinical trial of Evaluation of Methimazole 5% cream effectiveness versus Hydroquinone 2% cream to reduce melasma. Design: 50 patients with melasma in two groups of patients as controls and cases, each group consisted of 25 patients. Both treatment and advantages and disadvantages of each will be explained. Setting and conduct: At first patients will be asked to vote thyroid function tests. Cases will be treated with Methimazole 5% cream nightly for 8 weeks. The control group will be treated with Hydroquinone 2% cream nightly for 8 weeks. Inclusion criteria: Ages from 18 to 50; Normal to dry skin; without comedones Exclusion criteria: Absence of fallow up by patients and not satisfied to continue; Complications such as allergy to topical agent; Pregnancy and lactation; Thyroid disease; Oral contraceptive pills use and other drugs that cause melasma Intervention: The response to treatment based on visioface images. Outcome measures variables: Data collection is done by forms of patient information concerning the patient information, age and co morbidity. Then patients will be reassessing to evaluate response to treatment visioface photography and MASI system. In order to ensure that the drug's effect on thyroid hormones, again, thyroid function tests for patients will be asked at the end of the period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016073129145N1**
Registration date: **2016-12-05, 1395/09/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-05, 1395/09/15

Registrant information

Name

Sedighe Naeji

Name of organization / entity

Iran University Of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences.

Expected recruitment start date

2016-08-05, 1395/05/15

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Methimazole 5% cream effectiveness versus Hydroquinone cream 2% in patient with melasma, referred to Dermatology Clinic

Public title

Clinical trial of evaluation of Methimazole 5% cream effectiveness versus Hydroquinone cream 2% to reduce pregnancy spots (melasma)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Ages from 18 to 50; Normal to dry skin; without comedones Exclusion criteria: Absence of follow up by patients and not satisfied to continue; Complications such as allergy to topical agent; Pregnancy and lactation; Thyroid disease; Oral contraceptive pills use and other drugs that cause melasma.

Age

From **18 days** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University Of Medical Sciences, Adjacent to the Milad Tower, Hemat Highway, Tehran

City

Tehran

Postal code

Approval date

2015-11-30, 1394/09/09

Ethics committee reference number

IR.IUMS.REC.1394.27226

Health conditions studied

1

Description of health condition studied

melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Hyperpigmentation of face skin

Timepoint

At first and 8 weeks after treatment

Method of measurement

Intensity of the darkening of the face skin compared to other areas of the face with visioface device.

Secondary outcomes

1

Description

Satisfaction amount

Timepoint

After completion of treatment

Method of measurement

Comparison of reduction hyperpigmentation by patient, before and after treatment According to schedule

Intervention groups

1

Description

Intervention group 1: Cases will be treated with Methimazole 5% topical cream once a night for 8 weeks.

Category

Treatment - Drugs

2

Description

Intervenion group 2: The control group will be treated with Hydroquinone topical cream 2% once a night for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

Sedighe Naeji

Street address

Darmatology clinic, Hazrat Rasool Akram Hospital, Niayesh Steet, Shahr Aara, Sattarkhan Street, Tehran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person
Dr Seyed Ali Javad Mousavi

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Tehran

Grant name
-

Grant code / Reference number
-

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Iran 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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Position
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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