

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Topical Cysteamine cream in the treatment of epidermal melasma: A double blind randomized placebo controlled trial

Protocol summary

Summary

In this double-blind randomized clinical trial, Cysteamine hydrochloride cream (new skin depigmenting agent) is investigated in the treatment of melasma, and Consecutive Sampling is done. Inclusion criteria are: men and women aged 18 to 50 years; skin types III, IV, V, epidermal melasma approved by wood light; melasma for more than 6 months; patient who are able to read, understand and sign the consent form for periodic visits. The patients are divided in two groups of 25 with block randomization. Cysteamine and placebo will be applied for four months, once daily. Dermal or mixed type melasma, patients with any chronic infection with treating medication, history of using OCP and corticosteroids at the time of or 3 months before entering the study, hormonal disorders and pregnant women and lactating mothers are excluded. Expected outcome are clinical improvement; calculation MASI scores before and after 2 and 4 months of application of topical creams (Cysteamine or placebo) and also melasma pigmentation measured by Mexameter before and after 2 and 4 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212059800N2**
Registration date: **2013-03-13, 1391/12/23**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-03-13, 1391/12/23

Registrant information

Name

Parvin Mansouri

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Skin stem cell research center, Tehran University of Medical sciences

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2014-04-04, 1393/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Topical Cysteamine cream in the treatment of epidermal melasma: A double blind randomized placebo controlled trial

Public title

Effectiveness of Topical Cysteamine cream in the treatment of epidermal melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: men and women aged 18 to 50 years; skin types III, IV, V, epidermal melasma diagnosis confirmed by a wood light; Melasma duration for more than 6 months. Exclusion criteria: dermal and mixed type

of melasma; using OCP during the study and 3 months before entering the study; treatment with corticosteroids; hormonal disorders; pregnant and lactating mothers.

Age

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

Gender

Both

Phase

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

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences and Health Services

Street address

Ghodss St., Keshavarz Blvd

City

Tehran

Postal code

1417653761

Approval date

2012-11-17, 1391/08/27

Ethics committee reference number

91-03-150-19422-67930

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

L81.1

ICD-10 code description

Melasma

Primary outcomes

1

Description

mexameter changes

Timepoint

Before intervention, 2 & 4 months after intervention

Method of measurement

Erythema & Melanin measured by Mexameter

Secondary outcomes

1

Description

Patient clinical improvement

Timepoint

Before intervention, 2 & 4 months after intervention

Method of measurement

Physician's global score (inspection & comparing the photos)

2

Description

MASI Score

Timepoint

Before intervention, 2 & 4 months after intervention

Method of measurement

Physician's global score (inspection & comparing the photos)

3

Description

MASI score

Timepoint

Before intervention, 2 & 4 months after intervention

Method of measurement

Erythema and pigment measured by Dermacatch

Intervention groups

1

Description

Intervention 2: Vehicle cream in control group for 4 months, once in a day

Category

Placebo

2

Description

Intervention 1: Cysteamine cream in intervention group for 4 months, once in a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin clinic of Imam Khomeini hospital

Full name of responsible person

Dr. Parvin Mansouri

Street address

Imam Khomeini hospital

City

Tehran

2

Recruitment center

Name of recruitment center

Skin Clinic of Dr Mansouri

Full name of responsible person

Dr. Parvin Mansouri

Street address

No.458,Mahan Building,Yousef Abad

City

Tehran

3

Recruitment center

Name of recruitment center

Skin and Stem Cell Research Center

Full name of responsible person

Dr. Parvin Mansouri

Street address

No.4, Maryam Dd., Kamranyeh

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Parvin Mansouri

Street address

Skin Ward,Imam Khomeini Hospital

City

Tehran

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

Yes

Title of funding source

Tehran 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**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Susan Farshi

Position

MD, MPH

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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Dr. Parvin Mansouri

Position

Professor of dermatology

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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