Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Skin & Stem cell research centere, Dermatology department, Imam khomeini hospital, Tehran uni
Full name of responsible person
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Professor of dermatology
Other areas of specialty/work
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Tehran Univeristy of Medical Science
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Position

Dermatology,Professor

Other areas of specialty/work

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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