

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the therapeutic efficacy of cysteamine 5% cream with Hydroquinon 4% cream in epidermal melasma patients

Protocol summary

Study aim

Determination and comparison of the effect of cysteamine 5% cream and hydroquinone 4% cream in treatment of epidermal melasma

Design

Phase 3, parallel group, clinical trial, with consecutive sampling, including 98 patients, single blinded, computerized randomized with permuted blocks

Settings and conduct

The study is conducted in the dermatology clinic of Shiraz University of Medical Sciences. Group 1 applied cysteamine 5% cream and group 2 applied hydroquinone 4% cream nightly on the face. The patients are assessed at the beginning of treatment, 2nd month and 4th month by SkinColorCatch and photography by Visioface. The investigator is blind to the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 18 to 50 years; epidermal melasma
Exclusion criteria: dermal melasma; consumption of melasma causing medications; consumption of melasma treatments; pregnancy; lactation

Intervention groups

Group 1: Cysteamine 5% cream
Group 2: Hydroquinone 4% cream

Main outcome variables

Measuring melanin index; Determination of modified melasma area severity index score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140212016557N4**

Registration date: **2018-10-22, 1397/07/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-22, 1397/07/30**

Update count: **0**

Registration date

2018-10-22, 1397/07/30

Registrant information

Name

Mozhdeh Sepaskhah

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 712125239

Email address

sepaskhah@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-16, 1396/12/25

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic efficacy of cysteamine 5% cream with Hydroquinon 4% cream in epidermal melasma patients

Public title

Comparison of the effect of cysteamine cream and hydroquinone cream in the treatment of melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Epidermal melasma confirmed by Wood's lamp Duration of melasma more than 6 months Age 18 to 50 years

Exclusion criteria:

Dermal melasma OCP consumption during or in the past 3 months before the study Consumption of oral or topical corticosteroids on the site of melasma during the study Intolerance to hydroquinone or cysteamine as severe irritation Other pigmentary disorders Pregnancy Lactation

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants were randomized using permuted block randomization (size of each block: 4), in individual units, using random allocation software. The medications are in the similar tubes labeled by numbers of the patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

Despite of close similarity of medications tubes, the participants cannot be blind because of the different instructions for use. Principle investigator, the drug presentation staff, and care provider physician are also aware of the type pf drugs. But, data collectors and outcome assessors are not aware of the medication of each patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Imam Husain square, Zand St.

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2018-07-16, 1397/04/25

Ethics committee reference number

IR.SUMS.MED.REC.1397.181

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Melanin index

Timepoint

before intervention and 2 and 4 months after intervention

Method of measurement

SkinColorCatch instrument

Secondary outcomes

1

Description

modified Melasma Area and Severity Scale score

Timepoint

before intervention and 2 and 4 months after intervention

Method of measurement

modified Melasma Area and Severity Scale score formula

2

Description

Lee's investigator global assessment score

Timepoint

2 and 4 months after intervention

Method of measurement

5-point Likert scale for Lee's investigator global assessment score

3

Description

Lee's patient global assessment score

Timepoint

2 and 4 months after intervention

Method of measurement

5-point Likert scale for Lee's patient global assessment score

Intervention groups

1

Description

Intervention group: Cysteamine 5% cream (Scentispharma, Switzerland) is applied once every night for 15 minutes for 4 months on the face skin.

Category

Treatment - Drugs

2

Description

Control group: Hydroquinone 4% cream which is made by dissolution of 2 grams powder of hydroquinone (Merck, Germany) and 1.5 grams ascorbic acid powder (Merck, Germany) in 50 grams of vanishing cream (Minoo, Iran) is applied once every night overnight for 4 months on the face skin.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic, Shahid Faghihi hospital

Full name of responsible person

Mozhdeh Sepaskhah

Street address

Dermatology clinic, Faghihi hospital, Zand St.

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7134844119

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Email

sepaskhah@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Yunos Ghasemi

Street address

Research Council, Shiraz University of Medical Sciences, Zand St

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Grant name

Research grant of the Research Council of Shiraz University of Medical Sciences

Grant code / Reference number

1396-01-01-16288

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mozhdeh Sepaskhah

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

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

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available