Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 cyseamine 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: Ĩydroquinone 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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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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1433671348
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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 updating data

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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