

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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.

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3212 5239

##### 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

##### City

Shiraz

##### Province

Fars

##### Postal code

1433671348

##### Phone

+98 71 3212 2430

##### Email

vcrdep@sums.ac.ir

#### 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

##### Street address

Dermatology clinic, Faghihi hospital, Zand St.

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3212 5239

##### Email

sepaskhah@sums.ac.ir

## Person responsible for scientific 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

**Street address**

Dermatology clinic, Faghihi hospital, Zand St.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Phone**

+98 71 3212 5239

**Fax**

+98 71 3231 9049

**Email**

sepaskhah@sums.ac.ir

**Person responsible for updating data****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

**Street address**

Dermatology clinic, Faghihi hospital, Zand St.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Phone**

+98 71 3212 5239

**Fax**

+98 71 3231 9049

**Email**

sepaskhah@sums.ac.ir

**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