

# 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 acne-induced postinflammatory hyperpigmentation patients

#### Protocol summary

##### Study aim

Determination and comparison of the effect of cysteamine 5% cream and hydroquinone 4% cream in treatment of acne-induced postinflammatory hyperpigmentation

##### Design

Phase 3, parallel group, clinical trial, with consecutive sampling, including 50 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 14 to 40 years; facial acne post-inflammatory pigmentation; absence of active acne  
Exclusion criteria: consumption of depigmenting medication in the past 2 months; pregnancy; lactation; hypersensitivity to ingredients of drugs; patients taking oral contraceptive pills

##### Intervention groups

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

##### Main outcome variables

Measuring melanin index; Determination of postacne hyperpigmentation index (PAHPI)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140212016557N5**

Registration date: **2019-12-03, 1398/09/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-03, 1398/09/12**

Update count: **0**

##### Registration date

2019-12-03, 1398/09/12

##### 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

2019-04-06, 1398/01/17

##### Expected recruitment end date

2020-09-22, 1399/07/01

##### 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 acne-induced postinflammatory hyperpigmentation patients

**Public title**

Comparison of the effect of cysteamine cream and hydroquinone cream in the treatment of acne pigmentation

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Facial acne post-inflammatory hyperpigmentation No active acne lesion after or during treatment of acne

**Exclusion criteria:**

Receiving any depigmenting agent since 2 months before being recruited in the study Pregnancy Lactation History of hypersensitivity to ingredients of either drugs Patients taking oral contraceptive pills

**Age**

From **14 years** old to **40 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Investigator
- Outcome assessor

**Sample size**

Target sample size: **50**

**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 of 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**

2018-12-25, 1397/10/04

**Ethics committee reference number**

IR.SUMS.REC.1397.947

**Health conditions studied****1****Description of health condition studied**

Acne-induced post-inflammatory hyperpigmentation

**ICD-10 code**

L81.0

**ICD-10 code description**

Postinflammatory hyperpigmentation

**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**

Determination of postacnehyperpigmentation index (PAHPI)

**Timepoint**

before intervention and 2 and 4 months after intervention

**Method of measurement**

postacnehyperpigmentation index (PAHPI) formula

**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

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##### 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

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##### 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

97-01-01-18064

##### 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

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##### 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

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## 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**  
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Shiraz, Iran  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7134844119  
**Phone**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no further information.

### Study Protocol

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

### Statistical Analysis Plan

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

### Informed Consent Form

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

### Clinical Study Report

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

### Analytic Code

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

### Data Dictionary

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