

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 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

2018-12-25, 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

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

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

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

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Latest degree

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Other areas of specialty/work

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Postal code
7134844119
Phone
+98 71 3212 5239
Email
sepaskhah@sums.ac.ir

+98 712125239
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
Street address
Shiraz University of Medical Sciences, Zand St.,
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