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 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 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 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.

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Shiraz

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7134844119

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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

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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
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

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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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Person responsible for updating data

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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