

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy of 5% cysteamine vs 4% hydroquinone in melasma

Protocol summary

Study aim

To evaluate and compare the efficacy of 5% cysteamine cream and 4% hydroquinone cream in reducing melasma severity

Design

Study Design: Double-blind, Randomized Controlled trial
Study Setting: Combined Military Hospital, Quetta
Duration: 6 months
Sample Size: The sample size for this study was calculated using the WHO calculator and following parameters :- Level of significance (α): 5 %
Power of the test ($1-\beta$): 90 %
Anticipated Population Proportion 1 (P1): 0.249
Anticipated Population Proportion 1(P2): 0.389
Sample size (n): 228
Sampling Technique: Non probability consecutive sampling

Settings and conduct

Combined Military Hospital Quetta
Participants in cysteamine group will be instructed to apply a pea-sized amount of the assigned cream to the affected areas once daily at night as per following procedure :- 15 minutes for 1st 15 days. Subsequently, add 1 minute in 15 minutes everyday till 30th day. Continue to apply cream for 30 minutes for next 2 months. Participants in the hydroquinone group will apply thin layer over night for next 3 months. Patients will be assessed after every month for melasma according to MASI score. Picture will be captured at each visit for visual documentation and analysis.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: mild to moderate melasma (MASI score 4-24). Patients with epidermal and dermal hyperpigmentation. Patients with Fitzpatrick skin types III to V. Exclusion Criteria: Lactating and pregnant mother
Chronic underlying skin condition
Patient allergic to cysteamine and hydroquinone

Intervention groups

Melasma: An acquired pigmentary disorder characterized by hyperpigmented patches on sun-exposed areas of the skin. MASI Score: A validated measure used to quantify the severity of melasma, based on the area, darkness, and homogeneity of pigmentation.

Main outcome variables

Change in MASI score from baseline

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210823052264N13**

Registration date: **2025-01-09, 1403/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2025-01-09, 1403/10/20**

Update count: **0**

Registration date

2025-01-09, 1403/10/20

Registrant information

Name

Najia Ahmed

Name of organization / entity

PNS shifa

Country

Pakistan

Phone

+92 81 2864092

Email address

najiaomer@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-01, 1403/10/12

Expected recruitment end date

2025-06-01, 1404/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
 Efficacy of 5% cysteamine vs 4% hydroquinone in melasma

Public title
 Efficacy of 5% cysteamine vs 4% hydroquinone in melasma

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Adults aged 18-50 years with a clinical diagnosis of mild to moderate melasma (MASI score 4-24). Patients with Fitzpatrick skin types III to V . Patients with epidermal and dermal hyperpigmentation. Patients willing to use sun protection and adhere to treatment protocols.
Exclusion criteria:
 Patients with chronic underlying diseases like eczema
 Pregnant and breastfeeding Patients allergic to cysteamine and hydroquinone

Age
 From **18 years** old to **50 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Data analyser

Sample size
 Target sample size: **228**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Simple randomisation by lottery method Participants in cysteamine group will be instructed to apply a pea-sized amount of the assigned cream to the affected areas once daily at night as per following procedure :- 15 minutes for 1st 15 days. Subsequently, add 1 minute in 15 minutes everyday till 30th day. Continue to apply cream for 30 minutes for next 2 months. Participants in the hydroquinone group will apply thin layer over night for next 3 months. Patients will be assessed after every month for melasma according to MASI score. Picture will be captured at each visit for visual documentation and analysis.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Double blinded study. Participant and data analyzer are blinded.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees
1
Ethics committee
Name of ethics committee
 Institutional ethical review board(IERB) certificate
Street address
 Cmh quetta cantt
City
 Quetta
Postal code
 8251
Approval date
 2024-12-20, 1403/09/30
Ethics committee reference number
 CMH QTA-IERB/56/2024

Health conditions studied
1
Description of health condition studied
 Melasma
ICD-10 code
ICD-10 code description

Primary outcomes
1
Description
 Change in MASI score from baseline
Timepoint
 Before intervention, 1 month,2 month and 3 month
Method of measurement
 Photographic evidence and MASI score

Secondary outcomes
 empty

Intervention groups
1
Description
 Intervention group: Group A will be given 5% cysteamine at night
Category
 Treatment - Drugs
2
Description
 Intervention group: Group B will be given 4% hydroquinone at night
Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Cmh quetta

Full name of responsible person

Summra Pervaiz

Street address

Cmh quetta cantt

City

Quetta

Postal code

82971

Phone

+92 304 8075604

Email

summra.hassan6@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Cmh Quetta

Full name of responsible person

Summra Pervaiz

Street address

Cmh quetta cantt

City

Quetta

Postal code

82871

Phone

+92 304 8075604

Email

summra.hassan6@gmail.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Cmh Quetta

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

Cmh Quetta

Full name of responsible person

Summra Pervaiz

Position

Post graduate resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Cmh quetta cantt

City

Quetta

Province

Balochistan

Postal code

9286

Phone

+92 304 8075604

Email

summra.hassan6@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Cmh quetta

Full name of responsible person

Summra Pervaiz

Position

Post graduate resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Cmh quetta cantt

City

Quetta

Province

Balochistan

Postal code

9287

Phone

+92 304 8075604

Email

summra.hassan6@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Cmh quetta

Full name of responsible person

Summra Pervaiz

Position

Post graduate resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Cmh quetta cantt

City

Quetta

Province

Balochistan

Postal code

9287

Phone

+92 304 8075604

Email

summra.hassan6@gmail.com

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

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