Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Study 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-β) :90 % Anticipated Population Proportion 1 (P1): 0.249 Anticipated Population Proportion 1(P2): 0.38 9 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

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Cmh quetta
Full name of responsible person
Summra Pervaiz
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82971
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summra.hassan6@gmail.com

Sponsors / Funding sources

1

Sponsor

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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
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Person responsible for updating data

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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