Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy and Safety of Topical Metformin 30% in the Treatment of Melasma Compared to Triple Combination Cream(0.05% tretinoin, 2% hydroquinone, 0.01% fluocinolone acetonide)

Protocol summary

Study aim

To evaluate and compare the efficacy of topical metformin 30% versus triple combination cream in treatment of melasma.

Design

Community based, parallel group, double blind, randomized control trial

Settings and conduct

Participants of study meeting the inclusion criteria will be allotted two groups by lottery method of randomization. Melasma severity and Quality of life will be recorded as MASI score and MelasQoL respectively at the base line.Group A will receive topical metformin 30% cream at night while group B will receive topical triple combination cream at night.Participants will be blinded to what treatment they are getting. Both the groups will be assessed at 4 week, 8 week and 12 weeks and MASI, melasQoL, patient satisfaction and adverse effects will be recorded by an independent assessor. Participants will be assessed again at 16 week to assess recurrence. Study will be conducted at CMH, Quetta, Pakistan.

Participants/Inclusion and exclusion criteria

Inclusion Criteria- Adults aged 18- 60 with melasma, Fitzpatrick skin type III-V, no other melasma Exclusion Criteria: Use of photosensitizing drugs like phenytoin, tetracycline etc, pregnancy, lactation, renal disease, liver disease, history of recent laser treatment or hypersensitivity to metformin or triple combination cream

Intervention groups

Group A- topical metformin 30% cream at night Group B- topical triple combination cream at night

Main outcome variables

Primary Outcomes- Safety and efficacy Secondary outcomes- Quality of life, patient satisfaction, recurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210823052264N9**
Registration date: **2024-09-21, 1403/06/31**
Registration timing: **prospective**

Last update: **2024-09-21, 1403/06/31**
Update count: **0**

Registration date

2024-09-21, 1403/06/31

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

2024-09-24, 1403/07/03

Expected recruitment end date

2025-01-24, 1403/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy and Safety of Topical Metformin 30% in the Treatment of Melasma Compared to Triple Combination Cream(0.05% tretinoin, 2% hydroquinone, 0.01% fluocinolone acetonide)

Public title
Efficacy and Safety of Topical Metformin 30% in the Treatment of Melasma Compared to Triple Combination Cream(0.05% tretinoin, 2% hydroquinone, 0.01% fluocinolone acetonide)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Fitzpatrick skin types III- V No other melasma treatments in the last 6 weeks

Exclusion criteria:
Use of systemic photosensitizing drugs like phenytoin, tetracycline etc Pregnant or breastfeeding women Liver disease/ renal disease History of recent laser treatment or hypersensitivity to metformin or TCC.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Two groups are made by simple lottery method Group 1: Topical metformin 30% cream applied once daily at night. Group 2: Triple Combination Cream (0.05% tretinoin, 2% hydroquinone, 0.01% fluocinolone acetonide) applied once daily at night.

Blinding (investigator's opinion)
Double blinded

Blinding description
Double blind study (both 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 - CMH Quetta

Street address
Quetta

City
Quetta

Postal code
08762

Approval date
2024-09-24, 1403/07/03

Ethics committee reference number
CMH QTA-IERB /38/2024

Health conditions studied

1

Description of health condition studied
melasma

ICD-10 code
L81.1

ICD-10 code description
Chloasma

Primary outcomes

1

Description
Change in MASI scores from baseline

Timepoint
before intervention, 4week, 8 week, 12 week

Method of measurement
clinical examination and recording MASI score

2

Description
Incidence and severity of side effects (e.g., erythema, peeling, irritation, pigmentation).

Timepoint
4 weeks, 8 weeks, 12 weeks

Method of measurement
History and examination

Secondary outcomes

1

Description
Quality of Life

Timepoint
Baseline, 4 week, 8 weeks, 12 weeks

Method of measurement
Melasma Quality of life score (MelasQoL)

2

Description
Patient Satisfaction
Timepoint
4 weeks, 8 weeks, 12 weeks
Method of measurement
Subjective improvement giving scores from 1 to 4 (none, mild, moderate, marked improvement)

3

Description
Recurrence
Timepoint
16th week
Method of measurement
clinical examination

Intervention groups

1

Description
Intervention group: Group A will be given 30% topical metformin at night
Category
Treatment - Drugs

2

Description
Intervention group: Group B will be given Triple Combination Cream (0.05% tretinoin, 2% hydroquinone, 0.01% fluocinolone acetonide) applied once daily at night.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Combined Military Hospital, Quetta, Pakistan
Full name of responsible person
SAIMA ALI KHAN
Street address
Quetta
City
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Postal code
08762
Phone
+92 336 9947364
Email
saimaalikhan536x@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Combined Military Hospital, Quetta
Full name of responsible person
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Street address
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City
Quetta
Postal code
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Phone
+92 336 9947364
Email
saimaalikhan536x@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Combined Military Hospital, 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
Combined Military Hospital, Quetta
Full name of responsible person
SAIMA ALI KHAN
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
Combined Military Hospital, Quetta

Full name of responsible person
SAIMA ALI KHAN

Position
Assistant Professor

Latest degree
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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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