

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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		<u>1</u>	
Scientific title		Ethics committee	
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)		Name of ethics committee	Institutional ethical review board (IERB) certificate - CMH Quetta
Public title		Street address	Quetta
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)		City	Quetta
Purpose		Postal code	08762
Treatment		Approval date	2024-09-24, 1403/07/03
Inclusion/Exclusion criteria		Ethics committee reference number	CMH QTA-IERB /38/2024
Inclusion criteria:		Health conditions studied	
Fitzpatrick skin types III- V No other melasma treatments in the last 6 weeks		<u>1</u>	
Exclusion criteria:		Description of health condition studied	melasma
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.		ICD-10 code	L81.1
Age		ICD-10 code description	Chloasma
From 18 years old to 60 years old		Primary outcomes	
Gender		<u>1</u>	
Both		Description	Change in MASI scores from baseline
Phase		Timepoint	before intervention, 4week, 8 week, 12 week
3		Method of measurement	clinical examination and recording MASI score
Groups that have been masked		<u>2</u>	
- Participant - Data analyser		Description	Incidence and severity of side effects (e.g., erythema, peeling, irritation, pigmentation).
Sample size		Timepoint	4 weeks, 8 weeks, 12 weeks
Target sample size: 60		Method of measurement	History and examination
Randomization (investigator's opinion)		Secondary outcomes	
Randomized		<u>1</u>	
Randomization description		Description	Quality of Life
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.		Timepoint	Baseline, 4 week, 8 weeks, 12 weeks
Blinding (investigator's opinion)		Method of measurement	Melasma Quality of life score (MelasQoL)
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			

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

Quetta

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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

SAIMA ALI KHAN

Street address

Quetta

City

Quetta

Postal code

08762

Phone

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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

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Full name of responsible person

SAIMA ALI KHAN

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Person responsible for updating data

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Name of organization / entity

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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