

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Efficacy of oral melatonin vs oral tranexemic acid in the treatment of melasma

Protocol summary

Study aim

To compare the efficacy of oral melatonin 3mg vs oral tranexamic acid 250mg in the treatment of melasma

Design

open label Randomized Control Trial with 2 parallel group design of 180 patients enrolled between september 2026 and november 2026 in a single center

Settings and conduct

open label study Study design: randomized control trial Setting: Dermatology department MTI, Lady reading hospital. Duration: three months Sample size: 180, in which 90 will receive oral melatonin 3mg and the rest of the 90 participants will receive oral tranexamic acid Sampling technique: non probability consecutive sampling.

Participants/Inclusion and exclusion criteria

Inclusion Age 18-50 with clinically diagnosed melasma (centrofacial/malar/mandibular). Any gender; consent provided. Exclusion Pregnancy/lactation. Autoimmune disease, bleeding disorder, diabetes, prior thromboembolism, or renal impairment. Allergy to tranexamic acid or melatonin. Topical treatment on lesions within 4 weeks.

Intervention groups

A total of 180 patients with melasma fulfilling the inclusion criteria will be enrolled and randomized into two groups. Group A will receive oral melatonin 3 mg nightly, while Group B will receive oral tranexamic acid 250 mg twice daily, with sunscreen in both groups for 12 weeks. Efficacy will be assessed at 6 and 12 weeks using clinical photographs and mMASI scores, with >25% improvement considered effective.

Main outcome variables

To compare the efficacy of oral melatonin versus oral tranexamic acid in the treatment of melasma, assessed by the change in modified Melasma Area and Severity Index (mMASI) score from baseline to the end of treatment

General information

Reason for update

Acronym

efficacy of oral melatonin in melasma

IRCT registration information

IRCT registration number: **IRCT20260806070555N1**

Registration date: **2026-08-18, 1405/05/27**

Registration timing: **prospective**

Last update: **2026-08-18, 1405/05/27**

Update count: **0**

Registration date

2026-08-18, 1405/05/27

Registrant information

Name

Sadia Hameed

Name of organization / entity

Lady Reading Hospital

Country

Pakistan

Phone

+92 91 9211430

Email address

sadia.hameed@lrh.edu.pk

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-01, 1405/06/10

Expected recruitment end date

2026-11-30, 1405/09/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of oral melatonin vs oral tranexemic acid in the treatment of melasma

Public title

oral melatonin in Melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Patients of 18-50 years age diagnosed with melasma. Three clinical patterns associated with melasma i.e centrofacial, malar and mandibular will be examined Both genders

Exclusion criteria:

Pregnancy and lactation Patients with autoimmune disorders,bleeding disorders ,diabetes,history of thromboembolic events and renal impairment Patients with a history of hypersensitivity to oral tranexamic acid or melatonin Use of topical treatments eg topical hydroquinone, whitening agents, topical retinoids, and topical steroids on the affected area within 4 weeks prior to enrollment.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants will be recruited through non-probability consecutive sampling. After enrollment, participants will be randomly allocated in a 1:1 ratio to either the oral melatonin group or the oral tranexamic acid group using a simple lottery method. Sequentially numbered opaque sealed envelopes containing group assignments will be prepared before recruitment. Each participant will draw one envelope, and the assignment inside will determine the treatment group. Randomization will be performed at the individual participant level. Allocation concealment will be maintained until the envelope is opened at the time of assignment.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lady Reading Hospital /MTI(Institutional Review Board ,IRB)

Street address

Room no 5 (Research Cell), 4th Floor, Med Surge block, lady Reading hospital /MTI, Peshawar, KPK, Pakistan

City

Peshawar

Postal code

25000

Approval date

2026-08-06, 1405/05/15

Ethics committee reference number

700/LRH/mti

Health conditions studied

1

Description of health condition studied

Epidermal Melasma : Its characterized by hyperpigmented macules and patches on face due to excess melanin accumulation in the skin. It can be confirmed by woods lamp examination where the pigmentation becomes accentuated.

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Change in Melasma Area and Severity Index (MASI) score from baseline to 12 weeks after intervention.

Timepoint

before intervention and at 6 and 12 weeks after intervention

Method of measurement

Modified MASI score (Melasma Area severity index)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants will receive oral melatonin 3 mg once daily at bedtime for 12 weeks, along with standard sun protection measures and broad-spectrum sunscreen.

Category

Treatment - Drugs

2**Description**

Control group: Participants will receive oral tranexamic acid 250 mg twice daily for 12 weeks, along with standard sun protection measures and broad-spectrum sunscreen.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Lady Reading Hospital /MTI, Peshawar , pakistan

Full name of responsible person

Dr. Sadia Hameed

Street address

Dermatology unit, lady Reading hospital /MTI, Peshawar, KPK, Pakistan

City

Peshawar

Postal code

25000

Phone

+92 331 5175185

Fax**Email**

sadia.hameed@lrh.edu.pk

Web page address

<https://lrh.edu.pk/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Lady Reading Hospital /MTI

Full name of responsible person

Dr. Ali Talha Khalil

Street address

Office of the Associate Dean Research cell, room 5, 4th floor, med surg LRHMTI Peshawar, KPK, Pakistan

City

Peshawar

Postal code

25000

Phone

+92 332 9247627

Fax**Email**

alitalha.khalil@lrh.edu.pk

Web page address

<https://lrh.edu.pk/>

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

Yes

Title of funding source

Lady Reading Hospital /MTI

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**

Lady Reading Hospital /MTI

Full name of responsible person

Dr. Sadia Hameed

Position

Specialist Registrar

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Dermatology unit, lady Reading hospital /MTI, Peshawar, KPK, Pakistan

City

Peshawar

Province

Khyber Pakhtunkhwa

Postal code

25000

Phone

+92 331 5175185

Fax**Email**

sadia.hameed@lrh.edu.pk

Web page address

<https://lrh.edu.pk/>

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Lady Reading Hospital /MTI

Full name of responsible person

Dr. Sadia Hameed

Position

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Person responsible for updating data

Contact

Name of organization / entity

Lady Reading Hospital /MTI

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Dr. Sadia Hameed

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Web page address

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study Protocol for the randomized controlled trial "Oral Melatonin versus Oral Tranexamic Acid in the Treatment of Melasma." The study protocol will be made available upon reasonable request for academic and research purposes.

When the data will become available and for how long

The study protocol will be available after publication of the study and will remain available for 5 years.

To whom data/document is available

qualified researchers, academic institutions and health care professionals upon reasonable request to principal investigator

Under which criteria data/document could be used

The study protocol may be used for academic and research purposes. access will be granted upon reasonable request to principal investigator

From where data/document is obtainable

The study protocol can be obtained by contacting the Principal Investigator, Department of Dermatology, Lady Reading Hospital, Peshawar, Pakistan, via email or official correspondence.

What processes are involved for a request to access data/document

Interested researchers should submit a written request describing the purpose of use. Requests will be reviewed by the principal investigator, and access will be provided if deemed appropriate for academic or research purposes.

Comments

No additional comments