Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 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
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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, medsurg LRHMTI Peshawar, KPK, Pakistan
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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
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
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Person responsible for scientific inquiries

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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