

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Efficacy of Intralesional Tranexamic Acid Versus Topical 4% Hydroquinone in Treating Melasma

#### Protocol summary

##### Study aim

To compare the efficacy of intralesional tranexamic acid and topical 4% hydroquinone in the treatment of melasma

##### Design

Comparative prospective study

##### Settings and conduct

Study was conducted at the Dermatology Department, Pak Emirates Military Hospital Rawalpindi, Pakistan from 16th October 2018 to 16th April 2019.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Female patients of age 18-50 years with melasma for 6 months and not received any treatment in last 3 months. Exclusion Criteria: History of discoid lupus erythematosus, lichen planus on medical record, pregnancy, lactating mothers, anemia (Hb<10) and patients on oral contraceptive pills or hormonal therapy.

##### Intervention groups

Patients in Group A received weekly intradermal injections of 0.5 ml tranexamic acid in 0.5 ml normal saline (50 mg/ml) into the melasma lesion at 1 cm intervals using a sterile insulin syringe. Patients in Group B were given a topical hydroquinone 4% cream to apply to the relevant area at night for a period of 12 weeks. Follow up was done at 4 weekly intervals for 12 weeks. After 12 weeks final response was assessed. All patients were called for follow up and efficacy was evaluated on the basis of fall in MASI score from base line.

##### Main outcome variables

Efficacy was evaluated on the basis of fall in MASI score from base line.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220709055422N1**

Registration date: **2022-07-17, 1401/04/26**

Registration timing: **retrospective**

Last update: **2022-07-17, 1401/04/26**

Update count: **0**

##### Registration date

2022-07-17, 1401/04/26

##### Registrant information

###### Name

anjum muhammad

###### Name of organization / entity

Pak-Emirates Military Hospital Rawalpindi

###### Country

Pakistan

###### Phone

+92 334 9112468

###### Email address

anjumhassan87@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-16, 1397/07/24

##### Expected recruitment end date

2018-11-16, 1397/08/25

##### Actual recruitment start date

2018-10-16, 1397/07/24

##### Actual recruitment end date

2018-10-27, 1397/08/05

##### Trial completion date

2019-04-16, 1398/01/27

##### Scientific title

Comparison of Efficacy of Intralesional Tranexamic Acid Versus Topical 4% Hydroquinone in Treating Melasma

##### Public title

Efficacy of Tranexamic Acid Versus Topical 4%

Hydroquinone in Melasma

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

patients suffering from melasma

### Exclusion criteria:

history of discoid lupus erythematosus pregnancy  
lactation anemia oral contraceptives or hormone  
replacement therapy

## Age

From **18 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **290**

Actual sample size reached: **290**

## Randomization (investigator's opinion)

Randomized

## Randomization description

By using block design, we randomized the data. Randomization was 1:1 for Group A and Group B, i.e. each upcoming individual was included in the next group; this randomization was supervised by another clinician. Sample size for Group A (intralesional tranexamic acid) was 145 while sample size for Group B (topical 4% hydroquinone) was 145

## 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

Pak-Emirates Military Hospital Rawalpindi Ethical and Institutional Review Committee

##### Street address

PEMH Hospital Rawalpindi Cantonment

##### City

Rawalpindi

##### Postal code

46000

#### Approval date

2018-06-10, 1397/03/20

#### Ethics committee reference number

EC/A/28

## Health conditions studied

### 1

#### Description of health condition studied

Melasma .

#### ICD-10 code

L81.1

#### ICD-10 code description

L81.1 is a billable/specific ICD-10-CM code that can be used to indicate a diagnosis for reimbursement purposes. The 2022 edition of ICD-10-CM L81.1 became effective on October 1, 2021. This is the American ICD-10-CM version of L81.1 - other international

## Primary outcomes

### 1

#### Description

Efficacy was evaluated on the basis of fall in MASI score for Melasma from base line

#### Timepoint

Interventions were Offered for a period of 12 weeks. Follow up was done at 4 weekly intervals for 12 weeks. After 12 weeks final response was assessed. All patients were called for follow up and efficacy was evaluated on the basis of fall in MASI score from base line

#### Method of measurement

MASI score was measured by a trained physician on each visit

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients received weekly intradermal injections of 0.5 ml Tranexamic acid in 0.5 ml normal saline (50 mg/ml) into the melasma lesion at 1 cm intervals using a sterile insulin syringe.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Patients in intervention Group 2 were given a topical hydroquinone 4% cream to apply to the relevant area at night for a period of 12 weeks. Follow up was done at 4 weekly intervals for 12 weeks. After 12 weeks final response was assessed. All patients were called for follow up and efficacy was evaluated on the basis of fall in MASI score from base line. Patients who lost to follow up were contacted through their contact numbers and were reminded for their follow up visit.

#### Category

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Pak-Emirates Military Hospital Rawalpindi Ethical and Institutional Review Committee

**Full name of responsible person**

Dr Muhammad Rizwan

**Street address**

PEMH Hospital Rawalpindi Cantonment

**City**

Rawalpindi

**Postal code**

46000

**Phone**

+92 333 5373829

**Email**

rizwan\_rawalian2000@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Pak-Emirates Military Hospital Rawalpindi

**Full name of responsible person**

Ayesha Akhtar

**Street address**

PEMH Hospital Rawalpindi Cantonment

**City**

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**Postal code**

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**Phone**

+92 321 7324093

**Email**

suhailaisha1@gmail.com

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

No

**Title of funding source**

Pak-Emirates Military Hospital Rawalpindi

**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**

Pak-Emirates Military Hospital Rawalpindi

**Full name of responsible person**

Dr Muhammad Rizwan

**Position**

Consultant Dermatologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

PEMH Hospital Rawalpindi Cantonment

**City**

Rawalpindi

**Province**

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**Postal code**

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**Phone**

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**Email**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

PEMH Rawalpindi

**Full name of responsible person**

Dr Muhammad Rizwan

**Position**

Consultant Dermatologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

PEMH Rawalpindi

**Full name of responsible person**

Dr Muhammad Anjum

**Position**

Resident Dermatology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

PEMH Hospital Rawalpindi Cantonment

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

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**Email**

anjumhassan87@gmail.com

**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