

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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Rawalpindi

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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

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Rawalpindi

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46000

Phone

+92 321 7324093

Email

suhaailaisha1@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

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Province

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Postal code

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Email

rizwan_rawalian2000@gmail.com

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

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City

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Phone

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Email

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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