Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Offred 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

Treatment - Drugs

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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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

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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

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Person responsible for scientific inquiries

Contact

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PEMH Rawalpindi

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Position
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Medical doctor

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Person responsible for updating data

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Medical doctor
Other areas of specialty/work
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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