

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

To Compare the efficacy of Transamic acid (TA) mesotherapy vs Hydroquinone, Flucinolone acetonide and Tretinoin for melasma

Protocol summary

Study aim

To compare the efficacy of transamic acid mesotherapy versus Hydroquinone, flucinolone acetonide and tretinoin

Design

Clinical trial which is parallel group, double blind, randomized, phase 3 trial.

Settings and conduct

Dermatology department PNS Shifa hospital Karachi

Participants/Inclusion and exclusion criteria

Inclusion criteria Males and females 18-55 years with facial melasma Exclusion criteria Bleeding disorder, pregnant and lactating mothers

Intervention groups

Intervention group 1 Intradermal injection of Transamic acid into melasma areas at 2 weeks interval for 3 months. Intervention group 2 Treatment with topical Hydroquinone, flucinolone acetonide and tretinoin cream for 12 weeks.

Main outcome variables

The degree of melasma treatment

General information

Reason for update

Acronym

Mesotherapy

IRCT registration information

IRCT registration number: **IRCT20210823052264N1**

Registration date: **2021-09-29, 1400/07/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-29, 1400/07/07**

Update count: **0**

Registration date

2021-09-29, 1400/07/07

Registrant information

Name

Najia Ahmed

Name of organization / entity

PNS shifa

Country

Pakistan

Phone

+92 81 2864092

Email address

najiaomer@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-10, 1400/04/19

Expected recruitment end date

2021-11-10, 1400/08/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To Compare the efficacy of Transamic acid (TA) mesotherapy vs Hydroquinone, Flucinolone acetonide and Tretinoin for melasma

Public title

To Compare the efficacy of Transamic acid (TA) injection vs Hydroquinone, Flucinolone acetonide and Tretinoin for melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Males and females 18-55 years with facial melasma

Exclusion criteria:

Patients who has bleeding disorders, pregnant women and lactating mothers.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly divided into two groups on simple method based on sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant and data analyzer are blinded

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee PNS shifa

Street address

Main Korangi Rd, near Kala Pul. Clifton, Karachi

City

Karachi

Postal code

(021) 48506592

Approval date

2021-07-10, 1400/04/19

Ethics committee reference number

ERC/2021/DERMA/49

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The degree of melasma treatment

Timepoint

Before treatment, at 4th, 8th and 12th week during the treatment

Method of measurement

MASI Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In group A transamic acid is injected intradermally into melasma areas 1cm intervals every 2 weeks for 3 months.

Category

Treatment - Drugs

2

Description

Intervention group: Group B will be treated with topical Hydroquinone, Tretinoin and Fluocinolone Acetonide every night for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

PNS Shifa Hospital

Full name of responsible person

DR Muhammad Rahim

Street address

Main Korangi Rd, near Kala Pul. Clifton, Karachi, Karachi City, Sindh

City

Karachi

Postal code

74900

Phone

+92 21 48506592

Fax

+92 21 48506592

Email

drrahimachak@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

PNS SHIFA

Full name of responsible person

Dr muhammad rahim

Street address

Main Korangi Rd, near Kala Pul. clifton karachi

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krchi

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Email

achakzai89@gmail.com

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

Yes

Title of funding source

PNS SHIFA

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

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

PNS SHIFA

Full name of responsible person

Dr Muhammad Rahim

Position

Trainee

Latest degree

Bachelor

Other areas of specialty/work

Dermatology

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

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

pons shifa

Full name of responsible person

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Position

trainee

Latest degree

Bachelor

Other areas of specialty/work

Dermatology

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Email

drrahimachak@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

primary outcome

When the data will become available and for how long

1 month after publication

To whom data/document is available

All

Under which criteria data/document could be used

Many

From where data/document is obtainable

Email Address drrhimachak@gmail.com

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

Request

Comments

NA