Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Pakistan
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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 envelops.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participent 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 committe 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
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Karachi
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Email
drrahimachak@gmai.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
PNS SHIFA
Full name of responsible person
Dr muhammad rahim
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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
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 updating data

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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