Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Transxamic Acid(4mg/ml) Effects By Microneedling with Hydroquinone(4%) Ointment in Treatment of Melasma Patients.

Protocol summary

Study aim
Comparison of Tranexamic acid (4mg/ml) Effect By Microneedling with Hydroquinone(4%) in the Treatment Of Melasma Patients.

Design
Patients are coded into two groups A and B with simple randomization. Group A, receives hydroquinone ointment. Group B, undergoing microneedling with tranexamic acid. Patients are evaluated at intervals of weeks 0-4-8-12 by a researcher who is not aware of the codes, and informations is provided to a person who is not aware of the codes for statistical analysis. so, this study is one blinded .

Settings and conduct
This study is done in Dermatology Clinic of Afzalipour Hospital of Kerman and researcher who evaluates patients and the person who analyzing the information are blind to the study groups.

Participants/Inclusion and exclusion criteria
All women with melasma who did not have bleeding disorders, Hormontherapy , topical treatment like hydroquinone in the past year,active herpes, facial wart and hypersensivity to tranexamic acid & hydroquinone.

Intervention groups
Group A: Patients with melasma who receive ointment hydroquinone. Group B: Patients with melasma undergoing microneedling with tranexamic acid.

Main outcome variables
Demographic features(Age, Sex, Skin Type), Anatomic Location of melasma lesion and the rate of melasma lesions improvement at the end of the study.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180811040761N1**
Registration date: **2018-09-05, 1397/06/14**
Registration timing: **retrospective**

Last update: **2018-09-05, 1397/06/14**
Update count: **0**

Registration date
2018-09-05, 1397/06/14

Registrant information

Name
Hossein Mozayyeni

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3132 8237

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-14, 1397/05/23

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
2018-08-14, 1397/05/23

Actual recruitment end date
2018-08-23, 1397/06/01

Trial completion date
empty

Scientific title
Comparison of Transxamic Acid(4mg/ml) Effects By Microneedling with Hydroquinone(4%) Ointment in Treatment of Melasma Patients.

Public title
Effect Of Tranexamic acid By Microneedling in Melasma.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All Women with Melasma.

Exclusion criteria:

Coagulopathy Disease. Hormone Therapy. Topical treatment, like Hydroquinone, in the past year. Active Herpes. Facial Wart. Hypersensivity to Tranexamic acid & Hydroquinone. Pregnancy and Lactation.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned to two groups A and B, randomly.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are assigned to two groups A and B, randomly, and researcher who visits and evaluates patients and Also, the person who analyzes the data is not aware of these codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences.

Street address

Emam highway, Afzali Hospital, Dermatology Departement.

City

Kerman

Province

Kerman

Postal code

7616913911

Approval date

2018-08-13, 1397/05/22

Ethics committee reference number

IR.KMU.REC.1397.190

Health conditions studied

1

Description of health condition studied

Melasma.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Melasma intensity based on MASI (Melasma Area Severity Index) score.

Timepoint

(Melasma Area Severity Index) MASI Score measurement at the beginning of the study and weeks 4, 8,12.

Method of measurement

Using the Melasma Area Severity Index (MASI) Score.

2

Description

The rate of recovery of melasma lesions based on the Patient Global Assessment.

Timepoint

The rate of improvement of melasma lesions at the end of the study was based on the Patient Global Assessment questionnaire.

Method of measurement

Patient Global Assessment Questionnaire.

3

Description

The rate of recovery of melasma lesions based on the Patient Global Assessment.

Timepoint

The rate of improvement of melasma lesions at the end of the study was based on the Physician Global Assessment questionnaire.

Method of measurement

Physician Global Assessment Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients, mounthly, undergo

microneedling treatment with a concentration of 4 mg / ml of Tranexamic acid with Amiaemed, with a penetration depth of 1-1 / 2mm.

Category
Treatment - Drugs

2

Description
Control group: Patients treated with hydroquinone ointment 4% were treated for 3 months. Usage: nightly.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dermatology Clinic of Afzalipour Hospital.

Full name of responsible person
Hossein mozayyeni

Street address
Emam Highway, Afzali Hospital, Dermatology group.

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Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Abbas Pardakhti

Street address
Ebne sina street, tahmaseb abad Intersection.

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abpardakhty@kmu.ac.ir

Grant name
Annually grant

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kerman University of Medical Sciences

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
Kerman University of Medical Sciences

Full name of responsible person
Hossein Mozayyeni

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Simin Shamsi Meymandi

Position
Professor

Latest degree
Subspecialist

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Person responsible for updating data

Contact
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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
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
At the end of study, a part of the data, including the Melasma Area Severity Index, the Patient Global Assessment and the Physician Global Assessment (Unidentifiable)will be published.
When the data will become available and for how long
2 months after the results are published
To whom data/document is available
Researchers in the field of university and industry
Under which criteria data/document could be used
No analysis is allowed on data
From where data/document is obtainable
Hossein Mozayyeni h.mozayyeni@kmu.ac.ir 0098 9151365701
What processes are involved for a request to access data/document
The purpose of the message is to receive information By the applicant To email and review the request by the submitter
Comments