

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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, Hormonotherapy , topical treatment like hydroquinone in the past year,active herpes, facial wart and hypersensitivity 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

h.mozayyeni@kmu.ac.ir

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. Hypersensitivity 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.

City

Kerman

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+98 34 3132 8237

Email

h.mozayyeni@kmu.ac.ir

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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Email

abpardakhti@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

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Resident
Latest degree
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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