

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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.

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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

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Ebne sina street, tahmaseb abad Intersection.

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**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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Emam Highway, afzali Hospital, Dermatology unit

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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**

Dermatopathology

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## Person responsible for updating data

### 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**  
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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