

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Efficacy and safety of oral tranexamic acid in Melasema

Protocol summary

Summary

High prevalence of melasma and its great psychological impacts necessitate efficacious ,economical and safe therapeutic interventions. This study is a double - blinded randomized controlled clinical trial aiming to evaluate the efficacy and safety of tranexamic acid in the treatment of melasma. One hundred patients (age 18-65 years old) with symmetric facial melasma lesions, no history of cardiovascular diseases, cerebrovascular diseases and deep vein thrombosis which were not pregnant, lactating or undergone depigmentation therapy within 3 months prior to entrance into the study will be enrolled. Patients will randomly be divided into two groups. The intervention group will receive tranexamic acid , 250 mg orally thrice daily plus 4% hydroquinone cream once at night-time, while the control group will be treated only with 4% hydroquinone cream applied once nightly for a period of 3 months. Patients will be photographed after one and three months of treatment as well as three months after treatment discontinuation. Two independent and blinded dermatologists will assess clinical improvement using melasma area and severity index and relapse will be noted. Moreover,patients will be asked about treatment side effects and patient satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091914715N1**

Registration date: **2014-01-01, 1392/10/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-01-01, 1392/10/11

Registrant information

Name

Afsane Ghayoumi

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Reasearch of Tehran University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of oral tranexamic acid in Melasema

Public title

Efficacy and safety of oral tranexamic acid in Melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Age between 18 - 65 years old ; Symmetric distribution of melasma ; Informed consent.
Exclusion criteria : Usage of hydroquinone ,topical or oral retinoids ,topical corticosteroid ,alfa hydroxyl acids or other drugs effective to skin pigmentation 3 months prior to the study ; Usage of peeling agents 3 months prior to the study ; Laser therapy 3 months prior to the study ;

Sunburn , high exposure to sunlight or solarium usage 3 months prior to the study ; Usage of oral contraceptive concurrently ; Personal or familial history of vitiligo or other pigmentation disorders ; Suspected Hypersensitivity to hydroquinone or tranexamic acid ; Pregnancy or lactation ; History of ischemic heart disease or cerebrovascular disease ; History of coagulation disorders or deep vein thrombosis ; Usage of aspirin or Plavix.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

At the final visit , patients will be asked to characterize their overall satisfaction graded on a quartile scale as follows : complete satisfaction , moderate satisfaction , fair satisfaction and dissatisfaction.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics in Research Committee of Tehran University of Medical Sciences

Street address

Room 105 , 5th floor, Central construction of Tehran University of Medical Sciences , Ghods intersection , Keshavarz blvd.

City

Tehran

Postal code

1417653761

Approval date

2013-08-26, 1392/06/04

Ethics committee reference number

91/130/3630/3

Health conditions studied**1****Description of health condition studied**

Melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes**1****Description**

Improvement of pigmentation

Timepoint

Before the intervention, 1 and 3 months after the intervention and three months after discontinuation intervention

Method of measurement

MASI Score , Digital photography , Patient satisfaction

Secondary outcomes**1****Description**

Gastrointestinal complications

Timepoint

Before the intervention, 1 and 3 months after the intervention and three months after discontinuation intervention

Method of measurement

Question of patients

2**Description**

Reduce menstrual bleeding

Timepoint

Before the intervention, 1 and 3 months after the intervention and three months after discontinuation intervention

Method of measurement

Question of patients

Intervention groups**1****Description**

Intervention group : Tranexamic acid , 250 mg capsules , 3 times a day with hydroquinone 4% cream every night for 3 months.

Category

Treatment - Drugs

2

Description

Control group : Hydroquinone 4% cream every night for 3 months .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Dermatology Hospital

Full name of responsible person

Dr. Afsane Ghayoumi , Resident of Dermatology

Street address

Razi Dermatology Hospital , Vahdat Eslami sq. , Vahdat Eslami ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Reasearch of Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Younesian

Street address

Central Construction of Tehran University of Medical Sciences , Ghods intersection , Keshavarz blvd. Vice chancellor for research of Tehran University of Medical Sciences

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Tehran

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

Yes

Title of funding source

Vice Chancellor for Reasearch of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

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

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Afsane Ghayoumi

Position

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Dr. Vahide Lajevardi

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Assistant

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty