Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of therapeutic effect of oral and topical tranexamic acid in the treatment of patients with facial melasma receiving topical hydroquinone

Protocol summary

Summary

This study aimed to compare the therapeutic effect of oral and topical tranexamic acid in patients with melasma. The main inclusion criterion is the age between 20 and 70 years. The main exclusion criteria of the study are pregnancy; underlying skin disease; skin infection such as impetigo; the use of skin peeling therapies and a history of drug allergy. Among patients attending to dermatology clinic of Tabriz Sina Hospital with diagnosis of melasma, 90 patients will be divided in three groups of 30 subjects and will be studied. In the first group only hydroquinone cream, in the second group hydroquinone cream with tranexamic acid capsules orally, and in the third group hydroquinone cream and topical tranexamic acid will be used. Patients will be reviewed monthly and for each patient special forms will be filled out. Melasma severity depending on the extent of facial involvement, the degree of darkness and the homogeneity of the hyperpigmentation will be rated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411033566N7**
Registration date: **2014-11-20, 1393/08/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-11-20, 1393/08/29

Registrant information

Name

Hamide Azimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effect of oral and topical tranexamic acid in the treatment of patients with facial melasma receiving topical hydroquinone

Public title

Comparison of topical and oral treatments of melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion:patients with facial melasma; patients between 20 and 70 years old. Exclusion criteria: pregnancy; underlying skin diseases; thyroid disease; history of drug allergy; previous use of contraceptives or

phenytoin; patients with uncontrolled hypertension; patients with skin infections such as Impetigo; a history of coagulation or thrombosis; skin peeling treatments to treat existing disease; persons aged less than 20 years and more than 70 years old.

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Daneshgah Sq.

City
Tabriz

Postal code

Approval date
2014-09-29, 1393/07/07

Ethics committee reference number
93105

Health conditions studied

1

Description of health condition studied
Melasma

ICD-10 code
L81.1

ICD-10 code description
Chloasma

Primary outcomes

1

Description
The extent of facial skin involvement in percentage

Timepoint
At the first visit and then monthly up to 3 months.

Method of measurement
Usin MASI scoring system

2

Description
degree of melasma darkness compairing to normal skin

Timepoint
At the first visit and then monthly up to 3 months.

Method of measurement
Usin MASI scoring system

3

Description
Homogeneity of the melasma hyperpigmentation

Timepoint
At the first visit and then monthly up to 3 months.

Method of measurement
Usin MASI scoring system

Secondary outcomes

empty

Intervention groups

1

Description
The first group will only be treated with hydroquinone 2% cream evey night for 12 weeks.

Category
Treatment - Drugs

2

Description
The second group will be treated with hydroquinone 2% cream every night and tranexamic acid capsules 250 mg PO/BID for 12 weeks.

Category
Treatment - Drugs

3

Description
The third group will be treated with hydroquinone 2% cream every night and topical tranexamic acid cream 500mg daily for 12 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology Clinic of Sina Hospital
Full name of responsible person
Anali Sadeghi
Street address
Dermatology ward, Sina Hospital, Azadi Ave.
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Ali Reza Ostad Rahimi
Street address
Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Avenue, Daneshgah Square
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Anali Sadeghi
Position
MD, resident of Dermatology
Other areas of specialty/work
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Dermatology ward, Sina Hospital, Azadi Ave
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analisadeghi@gmail.com
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Person responsible for scientific inquiries

Contact
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Tabriz University of Medical Sciences
Full name of responsible person
Hamide Azimi
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Dermatologist/Associate professor
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Behzad Izadseresht
Position
Medical student
Other areas of specialty/work
Street address
Dermatology ward, Sina Hospital, Azadi Ave.
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Email
b.izadseresht@yahoo.com
Web page address

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