

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 41 1540 6612

Email address

azimih@tbzmed.ac.ir

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

Street address

Dermatology ward, Sina Hospital, Azadi Ave

City

Tabriz

Postal code

Phone

Fax

Email

analisadeghi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hamide Azimi

Position

Dermatologist/Associate professor

Other areas of specialty/work

Street address

Dermatology ward, Sina Hospital, Azadi Ave.

City

Tabriz

Postal code

Phone

Fax

Email

hamide-azimi@yahoo.com

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.

City

Tabriz

Postal code

Phone

Fax

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