

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of efficacy of oral Tranexamic Acid with 4% topical hydroquinone in the treatment of melasma.

Protocol summary

Study aim

Comparison of Oral Transxamic Acid Effect with 4% Local Hydroquinone in the Treatment of Melasma

Design

Patients are placed under a wood lamp examination and the type of melasma (dermal, epithelial, mixed, unspecified) is determined. It is explained to the patient about the manner in which the work is carried out and they are willing to obtain consent to enter the study. patients placed randomized in one of the groups A, which included administration of the topical hydroquinone 4% of the company Bahuzan, making Iran (cream Hydroquinone 4%) that is applied locally in the morning and night, or Group B containing the transaxamic acid capsule 250 mg of Amin Pharmaceutical Company, Iran (Trancid capsule 250 milligram) every 12 hours. Before the onset of each patient, the intensity of melasma was measured by the formula of the Melasma area and severity index (MASI) score and recorded separately for each patient. Each patient is treated for 3 months in each group for a period of 3 months and is followed up during the period and advised to use sunscreen (without anti-pigment content). Within 1 month and 3 months after starting treatment, each patient is reassessed and calculated for the MASI score. The sample size will be 31 in each group.

Settings and conduct

The study was performed on patients with melasma referred to Dermatology Clinic of Ahvaz Imam Khomeini Hospital. Imam Khomeini Hospital, Ahvaz Hospital. Dermatology clinic Blinding process ; As a record of the score of the MASI by a single person(the person with no knowledge from the patient group that studied) during the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with melasma aged 18 to 60 years. exclusion criteria: Patients with a history of coagulopathy, History of Thrombotic Problems Evidence for a thrombotic event, Using coagulant drugs, or

antiplatelets, such as aspirin or clopidogrel tablets, Pregnancy Lactation Concomitant use of contraceptives, The history of vitiligo or other pigmentation disorders, Trancexamic Acid Sensitivity History kidney disease, History of treatment for clarifying melasma during 3 months before the start of the study.

Intervention groups

Patients with melasma treated with Oral Transxamic Acid. Patients with melasma treated with topical hydroquinone 4%.

Main outcome variables

MASI SCORE. Sex Skin Phototype. Length of illness. family history. Type of melasma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180111038311N1**

Registration date: **2018-04-03, 1397/01/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-03, 1397/01/14**

Update count: **0**

Registration date

2018-04-03, 1397/01/14

Registrant information

Name

Samin Vala

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 2818

Email address

vala.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of oralTranexamicAcid with4% topical hydroquinone in the treatment of melasma.

Public title

Efficacy of oralTranexamicAcid in melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with melasma with 18- 60 years old rang.

Exclusion criteria:

Patients with coagulopathy Patients with thrombotic complications Any of thrombotic events Use of anticoagulant drugs or anti-platelet such as aspirin or Clopidogrel Pregnancy, lactation, concomitant use of contraceptives, The history of vitiligo or other pigmentation disorders, Trancexamic Acid Sensitivity History renal failure History of treatment for melasma with clarifying drugs in 3 months before the start of the study.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the quadrilateral permutation blocks, patients are randomly divided into two groups. This treatment is administered to both groups for 3 months.

Blinding (investigator's opinion)

Not blinded

Blinding description

As a record of the MASI score by a single person during the study, it does not have any information about the patient group being studied. During the treatment period, if the patient complains or does not want to

continue treatment, the study will be discontinued. During the sampling process, we will evaluate the MASI score as a baseline at the start of treatment, and at the 4th week - 12th and 3 months after the end of treatment, as well as at the end of the 3-month treatment, the patient's satisfaction with the treatment will be recorded in each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical sciences, Daneshgahi town, Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2017-08-23, 1396/06/01

Ethics committee reference number

IR.AJUMS.REC.1396.714

Health conditions studied

1

Description of health condition studied

Melasema

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

pigmentation

Timepoint

MASIS record before intervention - one month and three months after intervention

Method of measurement

MASI Score

Secondary outcomes

1

Description

Gastrointestinal complications

Timepoint

before intervention - one month and three months after intervention

Method of measurement

Ask the patients

2

Description

Hypomenorea

Timepoint

before intervention - one month and three months after intervention

Method of measurement

Ask the patients

Intervention groups

1

Description

Administration of the 250 mg Transxamic Acid Capsule Amin Pharmaceutical Company, Trancid capsule 250 milligram, is administered every 12 hours. On patients with melasma at the age of 18 to 60 years

Category

Treatment - Drugs

2

Description

Control group: Administration of topical Hydroconjun 4% of Behzan Company, Iran (Cream Hydroquinone 4%), which is applied locally in the morning and night. On patients with melasma at the age of 18 to 60 years

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Ahvaz Imam Khomeini Hospital

Full name of responsible person

Samin Vala

Street address

Dermatology clinic, Eimam khomeini hospital, 24 metric Ave, Ahvaz

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6193673111

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saminvala@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Ground floor, Vice chancellor of research, Ahvaz Jundishapur University of Medical Sciences, Daneshgahi town, Ahvaz

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Samin Vala

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
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Full name of responsible person
Reza Yaghoobi
Position
professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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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

Yes - There is a plan to make this available

Title and more details about the data/document

The total potential data can be shared after denationalization of people.

When the data will become available and for how long

Start the access period 1 year after the results print.

To whom data/document is available

Only available to scholars working in academia .

Under which criteria data/document could be used

Only for statistical analysis or use in multi-center designs.

From where data/document is obtainable

samin vala saminvala@gmail.com 009891633114629

What processes are involved for a request to access data/document

Send request via academic email. we will Send the data file within one month from the time of request.

Comments