Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of efficacy of oralTranexamicAcid with4% 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
Khouzestan
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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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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6135715794
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Research@ajums.ac.ir
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
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Full name of responsible person
Reza Yaghoobi
Position
professor
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Specialist
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Person responsible for updating data

Contact
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Latest degree
Medical doctor
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vala.s@ajums.ac.ir

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