Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of topical tranexamic acid versus oral tranexamic acid in the treatment of melisma: a randomized, double-blind clinical trial.

Protocol summary

Study aim
Investigating the effect of topical tranexamic acid compared to oral tranexamic acid in patients with melasma

Design
Control-controlled clinical trial with parallel, double-blind, randomized, phase 3 groups on 50 patients. In order to randomize, the block random allocation method was used.

Settings and conduct
This study will be performed on patients with melasma referred to Khatam Al-Anbia Clinic in Yazd. 25 patients in the first group will receive 5% topical tranexamic acid cream and 25 patients in the second group will receive 250 mg tranexamic acid capsules orally twice a day.

Participants/Inclusion and exclusion criteria
Inclusion criteria: omen with melasma from 18 to 60 years MMASI score greater than 8.5 Do not use oral contraceptives The patient has not received medication to treat melasma in the last three months Exclusion criteria: Drug Allergy Breastfeeding

Intervention groups
In order to compare the effectiveness of tranexamic acid cream with its oral capsule in the treatment of melasma, we give a group of 25 people transexamic acid cream and a group of 25 people tranexamic acid oral capsule.

Main outcome variables
Melasma intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181208041882N9**
Registration date: **2023-10-09, 1402/07/17**
Registration timing: **retrospective**
Last update: **2023-10-09, 1402/07/17**
Update count: **0**

Registration date
2023-10-09, 1402/07/17

Registrant information

Name
behrooz heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3820 8699

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b.heydari@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-20, 1401/02/30

Expected recruitment end date
2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of topical tranexamic acid versus oral tranexamic acid in the treatment of melisma: a randomized, double-blind clinical trial.

Public title
Evaluation of topical tranexamic acid effectiveness in the treatment of melasma

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women with melasma from 18 to 60 years MMASI score greater than 8.5 Do not use oral contraceptives The patient has not received medication to treat melasma in the last three months
Exclusion criteria:
Drug allergy Breastfeeding

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 50 patients were randomly divided into two treatment groups (A and B). In order to randomize, the block random allocation method was used, in which 10 blocks of 5 were considered. The letters A and B. These permutations were generated with the help of Random software distribution software version 1. For this purpose, the list prepared by software No. 1 to 50 is in 10 blocks of five in general to implement this I want the software output to the first eligible person number 1 and I want to select the last person number 50.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients, the physician, and the assessor of clinical symptoms will be all blinded to the intervention’s assignments during performing the study. In this way, the first executor of the sequence plan determines the allocation of individuals according to the order in which patients enter the study and delivers the appropriate medications to the patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yazd University of Medical Sciences
Street address
Shahid Sadoughi University of Medical Science, Shohadaye Gomnam Blvd, Alem Sq
City
Yazd
Province
Yazd
Postal code
8915173143

Approval date
2019-05-19, 1398/02/29

Ethics committee reference number
IR.SSU.MEDICINE.REC.1398.065

Health conditions studied

1

Description of health condition studied
Melasma

ICD-10 code
L81.1

ICD-10 code description
Chloasma

Primary outcomes

1

Description
Evaluation of of melasma improvement

Timepoint
Weeks 0, 4, 8

Method of measurement
MASI (Melasma Area Severity Index) Score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with melasma use Tranexamic acid capsules 250 mg orally twice a day for 8 weeks.

Category
Treatment - Drugs

2

Description
Intervention group: Patients with melasma use 5% tranexamic acid cream (manufactured in Yazd Faculty of Pharmacy) topically twice a day for 8 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam Al Anbia Clinic, Yazd

Full name of responsible person
Mohammad Ebrahimzadeh Ardakani

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Shahid Sadoughi University of medical sciences, Shohadaye Gomnan Blvd, Alem Sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Amin Salehi Abarghouei

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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
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Behrooz Heydari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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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
After nonrecognition, all data can be share
When the data will become available and for how long
6 months after publication
To whom data/document is available
All of researchers
Under which criteria data/document could be used
nothing
From where data/document is obtainable
Behrooz Heydari email: b.heydari@ssu.ac.ir
What processes are involved for a request to access data/document
Request your information by email. The data will be sent after a week.
Comments