

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 35 3820 8699

Email address

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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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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abargouei@ssu.ac.ir

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 scientific inquiries

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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