

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

the effect of topical tranexamic acid in compare with topical hydroquinone4% is used in women with melasma

Protocol summary

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Summary

in this interventional study;60 female patients come down with melasma that refer to the dermatologic clinic of the rasool hospital from 2015 to 2016;then are divided into two groups; interventional group and control group and then the intervention group treat with tranexamic acid twice a day;the control group use topical hydroquinone 4% at night;two groups in term of response to treatment will be evaluated and compared with each other at week 8 & 12. inclusion criteria: 1.female gender;2.suffering melasma exclusion criteria: 1.lack of compliance to continue the treatment;2.developed side effect of the treatment.

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Iran University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

MASI:melasma assessment severity index

IRCT registration information

IRCT registration number: **IRCT2016040627220N2**

Registration date: **2016-06-13, 1395/03/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-13, 1395/03/24

Registrant information

Name

Behzad Dalvand

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8835 0897

Email address

Scientific title

the effect of topical tranexamic acid in compare with topical hydroquinone4% is used in women with melasma

Public title

the effect of topical tranexamic acid in compare with topical hydroquinone4% is used in women with melasma

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 1.female gender,2.suffering melasma
exclusion criteria: 1.lack of compliance to continue the treatment,2.developed side effect of the treatment.

Age

No age limit

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: 60
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
accidental number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Iran University of Medical Sciences

Street address

Iran university-Hemmat highway

City

Tehran

Postal code

19922347512

Approval date

2015-05-23, 1394/03/02

Ethics committee reference number

IR.IUMS.REC.1394.9211166002

Health conditions studied

1

Description of health condition studied

melasma

ICD-10 code

L81.1

ICD-10 code description

chloasma

Primary outcomes

1

Description

melasma

Timepoint

8 weeks and 12 weeks later

Method of measurement

photography

Secondary outcomes

1

Description

rate of the lightening of the skin affected with melasma

Timepoint

8 weeks and 12 weeks later

Method of measurement

photography and determining rate of MASI

Intervention groups

1

Description

control group:apply topical hydroquinone4% seagull company nightly for 3 months

Category

Treatment - Drugs

2

Description

intervention group:apply topical tranexamic acid 5% manufactured by pharmacy of Hazrat Rasool Akram hospital of Tehran nightly for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool hospital

Full name of responsible person

Najm-alsadat atefi

Street address

Sattarkhan street-Niayesh street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research of Iran University of Medical Sciences

Full name of responsible person

Dr.Ali javad mousavi

Street address

Iran university-Hemmat highway

City

Tehran

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 of Iran 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
Iran University Medical Sciences
Full name of responsible person
Dr.Najm-alsadat atefi
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professor
Other areas of specialty/work
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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