Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Efficacy of Hydroquinone 2% cream versus Tranexamic Acid Injection in Treatment of Melasema

Protocol summary

Summary

(1) Objectives, Comparison of the Efficacy of Hydroquinone 2% cream versus Tranexamic Acid Injection in Treatment of Melasma. (2) design ,This trial is a clinical trial, and one side of the patient's face plays the role of control for the intervention on the other side, and the sample size is 37 patients, and it will be done in one dermatology center. (3) Setting and conduct, In this study, for one side of the patient, topical hydroquinone was used at night and on the other side of the tranexamic acid injection by a panel physician. And the patient will be paid for free during monthly intervals and will calculate the severity of the lesions and their recovery rate with the machine in the Moccoche and will record in the relevant information form. During this study, patients will be evaluated for the incidence of side effects and recurrence of the lesion, and the rate of melasma reduction in patients will be documented both subjectively and by the device in the mucocut. (4) Participants including major eligibility criteria, the people with melasma who do not have pregnancy and lactation and who have not used other clarifying compounds during the past 3 months can enter to the study.(5) Interventions. In this study, the concentration of 20 mg/ml of Tranexamic Acid for topical infusion will be used; it will be used by the physician in an intradermal setting at 1 cm intervals in place of melasma. 100 ml insulin is used to inject Nidal. After the local injection, the ice cream compressor will also be used. This process will be performed at intervals of 4 weeks for 3 months. (6) main outcome measures (primary and secondary outcome variables) include melasma and the amount of melanin in the skin, and the secondary variables include the patient's satisfaction subjectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040533244N1**
Registration date: **2017-09-20, 1396/06/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-09-20, 1396/06/29

Registrant information

Name

Mohammad Derayesh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 6682

Email address

darayesh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice counselor of Research of Shiraz University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy of Hydroquinone 2% cream versus Tranexamic Acid Injection in Treatment of

Melasema

Public title
Efficacy of Hydroquinone 2% cream versus Tranexamic Acid Injection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: All patients with melasma Exclusion criteria: Patients treated with steroids; Hydroquinone; Tretinoin; Azaleacic Acid and Kojic Acid; or pregnant; will be excluded. In addition, patients who have taken OCP over the past 12 months and who are taking light-sensitive drugs such as tetracycline; spironolactone; phenytoin and carbamazepine; or coagulation disorders and taking anticoagulant drugs will also be excluded.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **37**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
SUMS
Street address
Shiraz Zand st.
City
Shiraz
Postal code
7133613769
Approval date
2015-09-23, 1394/07/01
Ethics committee reference number
IR.SUMS.MED.REC.1396.02

2

Ethics committee
Name of ethics committee
SUMS
Street address
shiraz zand st.
City
shiraz
Postal code
Approval date
2017-08-20, 1396/05/29
Ethics committee reference number
IR.SUMS.MED.REC.1396.02

Health conditions studied

1

Description of health condition studied
Melasma
ICD-10 code
ICD-10 code description

2

Description of health condition studied
melasma
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Melasma and Melanin Density in Skin
Timepoint
Each 1 month
Method of measurement
Analysis with Dermacath

Secondary outcomes

1

Description
The Subjective Patient Satisfaction
Timepoint
After 3 month
Method of measurement
By VAS system

Intervention groups

1

Description
In this study, for one side of the patient, topical hydroquinone 2% is used at night.
Category
Treatment - Drugs

2

Description
On the other side, the tranexamic acid injection is used by the panel physician, with each side being randomly selected in each patient . During this study, patients will be evaluated for the incidence of side effects and recurrence of the lesion, and the rate of melasma reduction in patients will be documented both subjectively and by the device in the mucocut. In this study, the concentration of 20 mg / ml of Tranxamic Acid for topical infusion will be used; it is used by the physician in an interdermal setting at 1 cm intervals in place of melasma. 100 ml insulin is used to inject Nidal. After the local injection, the ice cream compressor will also be used. This process will be performed at intervals of 4 weeks for 3 months; then patients will follow a monthly follow up for 3 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz Shahid Faghihi Hospital

Full name of responsible person
Dr.Nasrin Saki

Street address
Shiraz Zand st.

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy of Research and Technology of Shiraz University of Medical Sciences

Full name of responsible person
Dr.Seied Basir Hashemi

Street address
Faghihi hospital , Zand st , Shiraz, Iran

City
Shiraz

Grant name

Grant code / Reference number

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

Title of funding source
Deputy of Research and Technology of Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Dr.Nasrin Saki

Position
Dermatologist

Other areas of specialty/work

Street address
Faghihi hospital ;Zand st ; Shiraz ; Iran

City
Shiraz

Postal code

Phone
+98 7109171180129

Fax

Email
nasrinsa85@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr.Nasrin Saki

Position
Dermatologist

Other areas of specialty/work

Street address
Faghihi Hospital ; Zand st ; Shiraz ; Iran

City
Shiraz

Postal code

Phone
+98 7109171180129

Fax

Email
nasrinsa85@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr.Mohammad Derayesh

Position
Dermatology Resident

Other areas of specialty/work

Street address
Faghihi Hospital ; Zand st; Shiraz ; Iran
City
Shiraz
Postal code
Phone
+98 71 3230 6682
Fax
Email
Web page address

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