Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Evaluation of the efficacy, safety and reliability of the effect of microneedling with tranexamic acid, in combination with a hydroquinone topical formula, in comparison with any of the treatments alone in patients with melasma: A randomized controlled clinical trial

Protocol summary

Study aim
Evaluation of the efficacy and safety of the effect of microneedling with tranexamic acid, in combination with a hydroquinone topical formula, in comparison with any of the treatments alone in patients with melasma

Design
Clinical trial with two intervention groups, parallel, single-blind, randomized, phase 2-3 on 50patients, randomized with randomization list prepared by the statistics specialist with specialized software.

Settings and conduct
Group A: Patients use the Kligman-like topical formula on one side of the face every other day for 2 months and microneedling with 10% tranhexamic acid on the other side for 3 sessions at intervals of 1 month. Group B: Patients use the Kligman-like topical formula for both sides of the face and in addition, on one side of the face, microneedling with tranhexamic acid 10% and on the opposite side microneedling with tranhexamic acid 4%.The second physician and statistics specialist are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 60 years old, Clinical diagnosis of bilateral melasma of the cheek Exclusion criteria: Patients who have received any treatment for melasma in the past 1 month. Contraindications to tranexamic acid. Mental instability. Patients who do not have informed consent to participate in the study. Patients who do not have the opportunity to visit regularly and cooperate for scoring and follow-up sessions

Intervention groups
Group A: Patients use the Kligman-like topical formula on one side of the face and microneedling with 10% tranhexamic acid on the other side. Group B: Patients use the Kligman-like topical formula for both sides of the face and in addition, on one side of the face, microneedling with tranhexamic acid 10% and on the opposite side microneedling with tranhexamic acid 4%.

Main outcome variables
Efficacy by modified Melasma Area & Severity Index and Visual Analogue Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220122053789N1**
Registration date: **2022-02-13, 1400/11/24**
Registration timing: **prospective**

Last update: **2022-02-13, 1400/11/24**
Update count: **0**

Registration date
2022-02-13, 1400/11/24

Registrant information

Name
Saba Baybordi Aghdam

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6435 2390

Email address
baybordi.s@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2022-03-16, 1400/12/25

Expected recruitment end date

2023-03-16, 1401/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy, safety and reliability of the effect of microneedling with tranexamic acid, in combination with a hydroquinone topical formula, in comparison with any of the treatments alone in patients with melasma: A randomized controlled clinical trial

Public title

Evaluation of the effect of microneedling with tranexamic acid in combination with hydroquinone formula in comparison with either alone in the treatment of melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years old Clinical diagnosis of bilateral melasma of the cheek

Exclusion criteria:

Patients who have received any treatment for melasma in the past 1 month. Patients who have contraindications to tranexamic acid. (Includes known drug allergy, intracranial hemorrhage, known color vision disorder, history of arterial or venous thromboembolism or active thromboembolic disease, ischemic heart disease, and stroke) Patients with mental instability (which is expected to affect the study process). Patients who do not have informed consent to participate in the study. Patients who do not have the opportunity to visit regularly and cooperate for scoring and follow-up sessions.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into one of two groups A or B with an equal number by the randomization list prepared by the statistics specialist with specialized software. Each patient who have the inclusion criteria will be randomly admitted to one of the two treatment groups according to the randomization list. To choose which side of the face to be assigned to which of the two desired treatments, a simple random method will be performed by the doctor at the same time.

Blinding (investigator's opinion)

Single blinded

Blinding description

The second physician and statistics specialist are blind to the group in which each patient is located and the type of treatment performed on each side of the patient's face.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of medical scinces

Street address

Hazrat Rasool Akram hospital, Mansoori avenue, Sattarkhan street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2021-12-18, 1400/09/27

Ethics committee reference number

IR.IUMS.FMD.REC.1400.541

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Efficacy

Timepoint

One and two months after the start of treatment and one and four months after the end of treatment

Method of measurement

By modified Melasma Area & Severity Index and Visual Analogue Scale

Secondary outcomes

1

Description
Safety
Timepoint
One and two months after the start of treatment and one and four months after the end of treatment
Method of measurement
Ask from the patient for possible adverse effects

2

Description
Satisfaction
Timepoint
One and two months after the start of treatment and one and four months after the end of treatment
Method of measurement
Based on patient scoring

Intervention groups

1

Description
Intervention group A: Patients use the Kligman-like topical formula on one side of the face every other day for 2 months and microneedling with 10% tranhexamic acid on the other side for 3 sessions at intervals of 1 month.
Category
Treatment - Other

2

Description
Intervention group B: Patients use the Kligman-like topical formula for both sides of the face every other day for 2 months and in addition, on one side of the face, microneedling with tranhexamic acid 10% and on the opposite side microneedling with tranhexamic acid 4% for 3 sessions at intervals of 1 month.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool Akram hospital
Full name of responsible person
Azadeh Goodarzi
Street address
Hazrat Rasool Akram hospital, Mansoori avenue, Sattarkhan street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 2390
Email
azadeh_goodarzi1984@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hosein Keyvani
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
keyvani.h@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Azadeh Goodarzi
Position
Associate professor
Latest degree

Specialist

Other areas of specialty/work
Dermatology

Street address
Dermatology ward, Hazrat Rasool Akram hospital, Niayesh avenue, Satarkhan street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6651 7341

Email
azadeh_goodarzi1984@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Azadeh Goodarzi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address
Dermatology ward, Hazrat Rasool Akram hospital, Niayesh avenue, Satarkhan street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6651 7341

Email
azadeh_goodarzi1984@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Saba Baybordi Aghdam

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

Street address
Hazrat Rasool Akram hospital, Mansoori avenue, Sattarkhan street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6435 2390

Fax

Email
baybordi.s@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable