Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

1- Comparison of Efficacy, safty, satisfaction and treatment duribility of intradermal injection of 10% tranexamic acid versus 5% topical tranexamic acid cream in patients under treatment with topical Modified Kligman's formula plus fractional Q-switch 1064 Nd:YAG laser,Triple arm ,paralell groups,Assessor analysis blinded, Randomized controlled ,Clinical Traial

Protocol summary

Study aim

To evaluate the efficacy of Q-switched ND:YAG laser plus tranexamic acid (injection/topical) for melasma, compared to standard treatment with modified Kligman's formula.

Design

Randomized, three-arm, double-blind clinical trial with permuted block randomization؛ assessor and analyst blinded؛ minimum 15 patients per group؛ intention-to-treat analysis.

Settings and conduct

Conducted at dermatology clinic of Hazrat Fatemeh Hospital؛ patients enrolled after informed consent and randomized؛ outcomes (mMASI, VAS) assessed at baseline، 8 weeks and 1 month post-treatment؛ sunscreen use permitted during follow-up.

Participants/Inclusion and exclusion criteria

Aged 18 to 60 years؛ diagnosed with melasma on cheeks or forehead؛ patients referred to dermatology clinic of Rasul Akram Hospital؛ willing to provide informed consent؛ able to attend follow-up visits؛ no melasma treatment in past one month.Major exclusion criteria prior to randomization History of other inflammatory skin diseases in melasma areas, photosensitivity disorders, pregnancy or lactation, allergy to Kligman's formula, recent melasma treatments (past 3 months), uncontrolled systemic diseases, recent hormonal therapy, non-compliance risk, interfering scars/tattoos, Fitzpatrick skin type VI

Intervention groups

Control group: Q-switched ND:YAG 1064nm laser (2 sessions with 4-week intervals) plus modified Kligman’s formula every other night for 8 weeks. Injection group: same laser and cream as control plus intradermal 10% tranexamic acid injections (dose adjusted by lesion extent) at baseline, week 4, and week 8. Topical group: same laser and cream as control plus topical 5% tranexamic acid applied every other night alternating with Kligman’s formula for 8 weeks.

Main outcome variables

Melasma severity measured by mMASI score؛ symptom severity (pain, irritation) measured by Visual Analogue Scale؛ patient satisfaction and adverse events.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250522065847N1**
Registration date: **2025-08-08, 1404/05/17**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-08, 1404/05/17**
Update count: **0**

Registration date

2025-08-08, 1404/05/17

Registrant information

Name

Hamid Rahimi

Name of organization / entity

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-04-21, 1404/02/01
Expected recruitment end date
2026-03-21, 1405/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
1- Comparison of Efficacy, safty, satisfaction and treatment duribility of intradermal injection of 10% tranexamic acid versus 5% topical tranexamic acid cream in patients under treatment with topical Modified Kligman's formula plus fractional Q-switch 1064 Nd:YAG laser,Triple arm ,paralell groups,Assessor analysis blinded, Randomized controlled ,Clinical Traial

Public title
This trial compares intradermal 10% vs. topical 5% tranexamic acid for melasma treatment alongside modified Kligman’s formula and Q-switched Nd:YAG laser.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The study includes individuals with melasma presenting unilaterally, bilaterally, or on the forehead.
Exclusion criteria:
1. Presence of other inflammatory dermatoses in the affected areas (e.g., rosacea, lupus, atopic dermatitis)2. History of photosensitive disorders or use of photosensitizing medications3. Pregnancy or lactation at the time of study entry4. History of hypersensitivity or allergy to Kligman's formula or any of its components5. Undergoing effective treatments for melasma (e.g., laser therapy, chemical peeling, microneedling) within the past 3 months6. Uncontrolled systemic diseases (e.g., uncontrolled diabetes, active hepatic or renal disease)7. Use of hormonal medications (e.g., oral contraceptives or hormone therapy) within the past 3 months8. Lack of willingness to adhere to treatment protocols or attend follow-up visits9. Presence of prominent scars or tattoos in the melasma-affected areas that may interfere with evaluation
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Here's the English translation of your text in a clear and academic tone: Randomization and Allocation Method: In the present study, participants will be allocated to groups using permuted block randomization. First, a randomization sequence will be generated by the researchers, followed by participant recruitment. Blocks of three will be formed, and blocks will be selected randomly until the required sample size is achieved. To maintain allocation concealment, the interventions will be coded as A, B, and C, without revealing the actual treatment names. This process ensures randomization concealment. Allocation to groups, patient enrollment, and treatment side designation will be performed by the first assessor according to the described protocol. In cases of protocol deviations, including issues related to treatment allocation, randomization, or follow-up completion, intention-to-treat (ITT) analysis will be employed. Only participants with at least 80% compliance will be included in the analysis. Those with lower compliance will be excluded from the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
The present study will be conducted in a double-blind manner, meaning that both the assessor and the data analyst will be blinded to the group allocation and the type of treatment administered to each participant.
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 Sciences"
Street address
Iran University of Medical Sciences Shahid Hemmat Highway (beside Milad Tower), Kooy Nasr (Kuy-e Nasr), Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date

2025-03-21, 1404/01/01

Ethics committee reference number

IR.IUMS.FMD.REC.1404.004

Health conditions studied

1

Description of health condition studied

Melasema

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Melasma severity is evaluated based on the Melasma Area and Severity Index (MASI) score in the forehead, right malar, and left malar regions. The MASI score incorporates assessment of involved area, pigmentation intensity, and homogeneity of the lesion.

Timepoint

MASI is measured at baseline (before the start of treatment), one month after the start of treatment, and two months after the start of treatment.

Method of measurement

Clinical examination and recording of MASI score by a dermatologist using the standard calculation formula

2

Description

Overall patient satisfaction with the treatment outcome is assessed two months after the start of treatment using a 5-point ordinal scale (excellent, good, moderate, poor, no satisfaction).

Timepoint

At the end of the second month of treatment

Method of measurement

Patient interview and recording of response using an ordinal scale form

Secondary outcomes

1

Description

The intensity of itching in the treated area

Timepoint

Immediately after treatment, one week after treatment, and one month after treatment

Method of measurement

Patient-reported numerical rating scale from zero (no itching) to ten (worst imaginable itching)

2

Description

The intensity of burning sensation in the treated area

Timepoint

Immediately after treatment, one week after treatment, and one month after treatment

Method of measurement

Patient-reported numerical rating scale from zero (no burning) to ten (worst imaginable burning)

3

Description

Patient satisfaction level regarding treatment outcome

Timepoint

One month and two months after the beginning of treatment

Method of measurement

Patient-reported five-point Likert scale satisfaction questionnaire (from completely dissatisfied to completely satisfied)

Intervention groups

1

Description

Control group: :Participants in the control group receive fractional Q-switched 1064-nm ND:YAG laser therapy with melasma-specific settings (average energy 600 nm, 5 Hz, spot size = 5 mm, 1500 shots for full face or 300–400 shots per cheek). Two sessions are performed four weeks apart. Additionally, they apply a topical Modified Kligman’s formula consisting of hydroquinone 4 g, vitamin C 3 g, and retinol 3 cc in cold cream base up to 100 g, every other night for 8 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group 1: Participants receive intradermal injections of 10% tranexamic acid based on the severity of melasma: mild (0.5 cc), moderate (1 cc), severe (1.5–2 cc per cheek), up to 4 cc for the full face. Injections are administered in three sessions, each four weeks apart: at baseline (after first laser session), four weeks after the second laser session, and four weeks after completion of the second laser session.

Category

Treatment - Drugs

3

Description

Intervention group: Intervention group 2: Participants apply topical 5% tranexamic acid (Dermalift) and Modified Kligman’s formula every other night on the affected areas. The Modified Kligman’s formula contains hydroquinone 4 g, vitamin C 3 g, and retinol 3 cc in cold cream base up to 100 g. Treatment continues for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Fatemeh Super Specialty Plastic Surgery Hospital

Full name of responsible person
Hamid Rahimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Deputy of Research and Technology, Iran University of Medical Sciences

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Hemmat Highway, Beside Milad Tower, Deputy of Research, Iran University of Medical Sciences

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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
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
Hamid Rahimi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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

Title and more details about the data/document
De-identified individual participant data including age, gender, baseline and final MASI scores, type of intervention, and clinical outcomes. Only anonymized data with no identifying information will be shared.

When the data will become available and for how long
Data will be available six months after study completion and publication of the main results. The access period begins six months after the publication date

To whom data/document is available
Academic researchers and qualified research institutions with a formal request and a clear scientific objective.

Under which criteria data/document could be used
Data may only be used for research purposes such as meta-analyses, secondary data analysis, or validation of results. Requesters must sign a Data Use Agreement (DUA) prior to access.

From where data/document is obtainable
Requests should be submitted to the principal investigator:

What processes are involved for a request to access data/document
The request must be submitted formally via email to the principal investigator. Upon review and approval of the research purpose, a Data Use Agreement (DUA) will be sent. Once signed, data will be provided within 2–4 working weeks.

Comments
All data will be encrypted and shared in Excel or CSV format. Data sharing will comply with ethical research standards and participant confidentiality protection.