Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluating the effect of Elvatan k5+ for treatment of melasma

Protocol summary

Study aim
Determination of the safety and efficacy of K5+ Elvatan© in the treatment of melasma

Design
This study is a randomized, double-blind, two-arm, parallel-group clinical trial conducted on 40 patients with melasma. Eligible participants are randomly allocated into two equal groups. The first group receives K5+ Elvatan cream and the second group receives topical tranexamic acid cream, both applied twice daily. Study outcomes are assessed at baseline, after one month, and after three months of treatment.

Settings and conduct
eligible patients visiting the dermatology clinic of Shahid Faghihi Hospital in Shiraz undergo baseline assessment of lesion severity, quality of life, and standardized photography. Identical treatments are then dispensed, alongside instructions on application and sunscreen use. Patients are re-evaluated at the end of months 1 and 3.

Participants/Inclusion and exclusion criteria
The inclusion criteria of our study will be: all of the patients between 18-60 years old who will be referred to Dermatology clinics of Shiraz University of Medical Sciences with a diagnosis of melasma who have not been treated with skin lightening agents in the past three months. The exclusion criteria of our study will be pregnant and breastfeeding women, chronic renal failure, cirrhosis, autoimmune disorders, previous history of deep vein thrombosis or pulmonary thromboembolism in the patient or their family members, and unwillingness to participate in the study.

Intervention groups
Intervention group: Participants in this group receive K5+ Elvatan cream, applied twice daily.
Control/comparator group: Participants in this group receive topical tranexamic acid cream, applied twice daily.

Main outcome variables
the primary outcomes of the study are changes in the Melasma Area and Severity Index (MASI) score and changes in the darkness of melasma lesions assessed by Visioface.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260514069400N1**
Registration date: **2026-10-09, 1405/07/17**
Registration timing: **retrospective**

Last update: **2026-10-09, 1405/07/17**
Update count: **0**

Registration date
2026-10-09, 1405/07/17

Registrant information

Name
latifeh habibi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3235 1087

Email address
latifahabibi92@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-21, 1405/03/31

Expected recruitment end date
2026-09-19, 1405/06/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of Elvatan k5+ for treatment of melasma

Public title
Elvatan k5+ for treatment of melasma

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients between 18-60 years old with a diagnosis of melasma not been treated with skin lightening agents in the past three months.

Exclusion criteria:
pregnant women breastfeeding women chronic renal failure and end-stage renal disease cirrhosis and end-stage liver disease autoimmune disorders such as systemic lupus erythematosus previous history of deep vein thrombosis or pulmonary thromboembolism in the patient or their family members unwillingness to participate in the study

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants will be randomly allocated into two equal groups (1:1 allocation ratio) using permuted block randomization with variable block sizes of 4 and 6 [և: fixed block size of 4]. The random allocation sequence will be generated prior to participant enrollment by an independent researcher using Random Allocation Software (Version 2.0, developed by M. Saghaei, Isfahan University of Medical Sciences, available at: https://mahmoodsaghaei.tripod.com/Softwares/randalloc.html). To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes (SNOSE) will be utilized. Each envelope, containing the assigned intervention code, will be opened sequentially by an independent coordinator only after participant enrollment and baseline clinical evaluation.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted as a double-blind clinical trial. K5+ Elvatan cream and topical tranexamic acid cream will be placed in identical containers in terms of shape, color, and size and will be labeled as Drug A and Drug B. Participants and the treating/evaluating physicians will be blinded to the allocated intervention, and only the pharmacist will be aware of the contents of each code.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Zand strret

City
shiraz

Province
Fars

Postal code
۷۱۳۴۸۱۴۳۳۶

Approval date
2025-07-22, 1404/04/31

Ethics committee reference number
IR.SUMS.MED.REC.1404.260

Health conditions studied

1

Description of health condition studied
melasma

ICD-10 code
L81.1

ICD-10 code description
Chloasma

Primary outcomes

1

Description
Change in Melasma Area and Severity Index (MASI) score

Timepoint
Baseline, one month after treatment initiation, and three months after treatment initiation

Method of measurement
MASI score will be assessed by a dermatologist/trained evaluator based on darkness, homogeneity, and area of facial involvement.

Secondary outcomes

1

Description
Change in the darkness of melasma lesions
Timepoint
Baseline, one month after treatment initiation, and three months after treatment initiation
Method of measurement
The darkness of melasma lesions will be assessed and recorded using Visioface imaging system.

2

Description
Change in dermatology-related quality of life
Timepoint
Baseline, one month after treatment initiation, and three months after treatment initiation
Method of measurement
Patients' quality of life will be assessed using the Persian version of the Dermatology Life Quality Index (DLQI) questionnaire.

3

Description
Change in melasma-specific quality of life
Timepoint
Baseline, one month after treatment initiation, and three months after treatment initiation
Method of measurement
Melasma-specific quality of life will be assessed using the Persian version of the Melasma Quality of Life (melasQOL) questionnaire.

4

Description
Global assessment of treatment response by patient and physician
Timepoint
One month after treatment initiation and three months after treatment initiation
Method of measurement
Treatment response will be assessed by the patient and two dermatologists using a five-point Likert scale ranging from -2, indicating significant worsening, to +2, indicating significant improvement. In case of disagreement, the opinion of the attending dermatologist will be recorded as the final assessment.

5

Description
Occurrence of possible drug-related adverse effects
Timepoint
Throughout the treatment period, one month after treatment initiation, and three months after treatment initiation
Method of measurement
Possible adverse effects will be recorded through patient history, clinical examination, and an adverse-effect checklist, including redness, itching, burning, skin irritation, dryness, hypersensitivity, or any other patient-reported adverse effects.

Intervention groups

1

Description
Intervention group: participants in the intervention group receive K5+ Elvatan cream, applied twice daily, in the morning and evening, to the melasma-affected areas. The duration of intervention is three months. Participants are evaluated at baseline, one month after treatment initiation, and three months after treatment initiation for melasma severity, quality of life, and possible adverse drug effects.
Category
Treatment - Drugs

2

Description
Control group: participants in the control/comparator group receive topical tranexamic acid cream, applied twice daily, in the morning and evening, to the melasma-affected areas. The duration of intervention is three months. Participants are evaluated at baseline, one month after treatment initiation, and three months after treatment initiation for melasma severity, quality of life, and possible adverse drug effects.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Latifeh Habibi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hamid Mohammadi
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Latifeh Habibi
Position
resident
Latest degree
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Person responsible for updating data

Contact

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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
No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

De-identified individual participant data (including demographic and clinical outcomes).

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

It will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Strictly for meta-analysis or scientific validation, after signing a data-use and confidentiality agreement.

From where data/document is obtainable

Latifeh Habibi

What processes are involved for a request to access data/document

Formal email request from the applicant -> Review by the research team -> University Ethics Committee approval (if required) -> Data sharing via secure email

Comments