Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Clinical assessment of the efficacy of tranexamic acid-niacinamide loaded niosome in comparison to tranexamic acid-niacinamide and hydroquinone conventional creams in melasma

Protocol summary

Study aim

The main purpose of this study is to assess the clinical efficacy of topical niosomal tranexamic acid-niacinamide formulation in melasma patients

Design

A randomized, double-blinded, parallel-group, controlled trial on 102 patients, randomization through the block randomization technique (block size: 6) using Sealedenvelope.com site.

Settings and conduct

This study will take place in the Dermatology clinic of Faghihi Hospital, Shiraz. Patients will be divided into 3 groups and visited before therapy and then monthly up to month 3. This study will be double-blinded and patients and physicians are blind to the therapeutic options.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients (male and female) with melasma between 18 and 50 years old; patients who have had melasma for at least 6 months, those who are capable of understand, read, and write and sign the informed consent form; and patients who are able to participate in sequential follow-up visits by physician. Exclusion criteria: Consumption of oral contraceptives; patients who are taking oral corticosteroids or topical corticosteroids on melasma lesions during the study; history of thyroid disorders, intolerance to the administered drugs; patients have had other hyperpigmentary disorders; pregnancy and lactation

Intervention groups

The first group will receive topical niosomal tranexamic acid-niacinamide, the second group will receive conventional tranexamic acid-niacinamide cream, and the third (control) group will receive conventional 4% hydroquinnone cream . All patients will receive the formulations twice daily for 3 months (except for the hydroquinone group that will receive the blinded-label cold cream in the morning).

Main outcome variables

Skin Photography and calculation of modified Melasma Area Severity Index (mMASI) score and melanin index. Assessment of Melasma Quality of Life Scale (MELASQOL) questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220609055116N1**
Registration date: **2023-07-23, 1402/05/01**
Registration timing: **prospective**

Last update: **2023-07-23, 1402/05/01**
Update count: **0**

Registration date

2023-07-23, 1402/05/01

Registrant information

Name

Soliman Mohammadi-Samani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2024-05-20, 1403/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical assessment of the efficacy of tranexamic acid-niacinamide loaded niosome in comparison to tranexamic acid-niacinamide and hydroquinone conventional creams in melasma

Public title

Clinical assessment of the efficacy of topical nano-formulation of tranexamic acid/niacinamide in melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients (Male/female) with melasma between 18 and 50 years old Patients who have had melasma for at least 6 months ago Patients who are capable to understand, read, and write the informed consent form Patients who are able to participate in periodic follow-up visits by physician

Exclusion criteria:

Patients who have received oral contraceptive (OCP) therapy within 3 months prior to the study initiation or during the study Patients who are receiving oral corticosteroids or applying topical corticosteroids on melasma lesions during the study Patients with a history of thyroid disease Patients with a history of intolerance, hypersensitivity reactions, or severe irritation to hydroquinone, tranexamic acid, or niacinamide, Patients with other hyperpigmentary disorders Pregnancy or lactation Patients who have received any pharmacologic or procedural treatment within 2 months prior to the study initiation

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into 3 treatment groups through the block randomization technique using Sealed Envelope software. Sealed Envelope software is used for block randomization of the samples. In this regard, the sample size (102 patients), the block size (6), and the number of treatment groups (3 groups) will be given to the software. Then, according to the inputs, a total of 102 patients will be randomly divided into 17 blocks and each block will contain 6 individuals. In addition, each block will contain an equal number of each treatment type. After that, through the Sealed Envelope software, a specified code number (ex. NB4) will be assigned to each patient. After formulation preparation according to the suggested blocks, each formulation will be put in an envelope and sealed, and then marked with a specified code number. The prepared sealed envelopes will be grouped in the aforementioned blocks and will be given to the physician. Each sealed envelope that is marked with a specified code number will be randomly allocated to each participant entered in the trial by the physician. So, the Sealed Envelope software will be used as a randomization tool and allocation concealment would be achieved through the sealed envelopes and specified codes that will be assigned to each participant. Only the principle investigator and the formulator will be aware of the treatment type of each sealed envelope and specified code number, while others are blinded.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, all participants, the physician who will visit the patients and assess the response to therapy sequentially, those who will give the formulations to the patients, the statistical analyst, and the outcome analyzer will be blinded. However, the principle investigator, Safety Monitoring Board, the researcher who prepared the formulations, and the manuscript writers will be unblinded. It should be mentioned that all patients will be aware of the clinical trial and will be included in this study just after signing the informed consent form. Blinding will be performed through the recruitment of the suggested specified code numbers by the Sealed Envelope software. In this regard, each treatment (topical formulation) would be put in an envelope and sealed, and marked with a specified code number from the software. After that, the sealed envelopes will be further grouped in blocks. The prepared sealed envelopes that are grouped in 17 blocks (each block contains 6 envelopes) will be given to the physician. The physician will randomly allocate each sealed envelope to each participant who entered the trial. Therefore, only the principle investigator, Safety Monitoring Board, and the formulator will be aware of the treatment type of each specified code number of sealed envelopes, while the others are blinded.

Placebo

Not 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

Ethics Committee, Vice Chancellor for Research, Administrative Buiding of Shiraz University of Medical Sciences, Zand Blvd, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2023-04-24, 1402/02/04

Ethics committee reference number

IR.SUMS.REC.1402.050

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

L81

ICD-10 code description

Other disorders of pigmentation

Primary outcomes

1

Description

In each follow-up, standard skin photography will be performed from the left, right, and front sides of the faces of the patients using Visioface 1000D instrument (CK Electronic, Germany) and modified melasma area and severity (mMASI) score, as a major assessment tool in melasma, will be calculated accordingly.

Timepoint

Clinical responses to the topical treatment will be assessed every 4 weeks up to 3 months in patients with melasma.

Method of measurement

Modified MASI score = 0.3 × Area (forehead) × Darkness (forehead) + 0.3 × Area (left malar) × Darkness (left malar) + 0.3 × Area (right malar) × Darkness (right malar) + 0.1 × Area (chin) × Darkness (chin)

Secondary outcomes

1

Description

Patients' quality of life will be assessed through the Melasma Quality of Life Scale (MELASQOL) questionnaire.

Timepoint

Patients' quality of life will be assessed before treatment initiation and also at the end of the study (after 3 months of treatment).

Method of measurement

Patients' quality of life will be assessed through the Melasma Quality of Life Scale (MELASQOL) questionnaire in which validity and reliability are confirmed.

Intervention groups

1

Description

First group: Patients receiving topical niosomal tranexamic acid %2-niacinamide %2 formulation twice daily for 3 months

Category

Treatment - Drugs

2

Description

Second group: Patients receiving topical tranexamic acid %5-niacinamide %4 conventional cream twice daily for 3 months

Category

Treatment - Drugs

3

Description

Positive control group: Patients receiving topical hydroquinone %4 conventional cream at night (and blinded-label cold cream in the morning) for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Shahid Faghihi Hospital

Full name of responsible person

Prof. Soliman Mohammadi-Samani

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Sponsors / Funding sources

1

Sponsor

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Grant name
27787

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
Prof. Soliman Mohammadi-Samani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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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
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All gathered deidentified individual participant data (IPD) would be shared where necessary.

When the data will become available and for how long
Data would be available after the collection of required data from all participants or when any severe adverse reaction occurred. Data would be available at least for 5 years after the completion of this study.

To whom data/document is available
Data would be available to healthcare authorities.

Under which criteria data/document could be used
Data would be available on request.

From where data/document is obtainable
Data would be available through direct communication with the project administrator.

What processes are involved for a request to access data/document
Data would be available through direct communication with the project administrator. (Email address: smsamani@sums.ac.ir)

Comments