Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of topical Methimazole 5% versus topical Hydroquinone 4% on the improvement of melasma lesions

Protocol summary

Study aim
main goal of the study: comparison of topical ۵% Methimazole and 4 % Hydroquinone effect on melasma
Design
Clinical trial with a control group in the same patient, without blinding and not randomized, phase 2-3 on 30 patients.
Settings and conduct
The studied patients are 30 patients with melasma and they visited the skin clinic of Sinai Hospital in the fall and winter of 1401. Methimazole 5% topical cream, which is formulated, is provided to the patients and they are asked to apply once a day to Apply this cream on the right side of your cheek and use 5% topical hydroquinone cream on the left side of your cheek.
Participants/Inclusion and exclusion criteria
Inclusion criteria 1)Age above 18 years and below 50 years 2)informed consent to participate in the study 3) presence of melasma on both sides of the cheeks Exclusion criteria ۱) having no consent to participate in the study 2) pregnancy or lactation 3) history of sensitivity to Tiamazoles 4) history of using other topical drugs for melanoma in past 3 months 5) thyroid dysfunction
Intervention groups
The formulated 5% topical methimazole cream is provided to the patients and they are asked to apply this cream once a day to the right side of their cheek and apply 5% topical hydroquinone cream to the left cheek. .
Main outcome variables
Severity of melasma lesions

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20091012002581N9**
Registration date: **2023-02-21, 1401/12/02**
Registration timing: **prospective**

Last update: **2023-02-21, 1401/12/02**
Update count: **0**
Registration date
2023-02-21, 1401/12/02

Registrant information
Name
Hamide Herizchi
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-03-06, 1401/12/15
Expected recruitment end date
2023-04-19, 1402/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of topical Methimazole 5% versus topical Hydroquinone 4% on the improvement of melasma lesions

Public title
Comparison of topical ۵% Methimazole and 4 %

Hydroquinone effect on melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age higher than 18 years and below 50 years Informed consent participate in the study Presence of melanoma in both sides of cheeks

Exclusion criteria:

Lack of consent to participate in the study Pregnancy or lactation History of sensitivity to Tiamazoles Thyroid dysfunction History of using other topical drugs for melanoma in past 3 months

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

the patient uses the Methimazole cream in one side of cheek and Hydroquinone in other side as in control

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for research of Tabriz University of Medical Sciences

Street address

Research centre , 3th floor, Central building number 2,Tabriz University of Medical Sciences,Golgasht street ,Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

۵۱۵۴۳۱۲۳۲

Approval date

2022-11-22, 1401/09/01

Ethics committee reference number

IR.TBZMED.REC.1401.771

Health conditions studied

1

Description of health condition studied

melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Severity of melasma lesions

Timepoint

1, 4, 8 and 12 months after treatment

Method of measurement

Clinical examination and comparison of photos and use of Hemi Masi score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 5% topical methymazole cream that has been formulated in Tabriz University of Medical Sciencses Faculty of Pharmacy, is provided to the patients and they are asked to apply this cream to the right side of their cheek once a day. Patients are followed up at intervals of 4, 8, and 12 weeks, and their recovery rate, satisfaction, and Masi score are checked for them. Thyroid function tests are also requested again in the 8th week. The side effects and recovery rate will be checked based on the mentioned cases at the end of the 12th week.

Category

Treatment - Drugs

2

Description

Control group: 5% topical hydroquinone cream that has been formulated in Tabriz University of Medical Sciences Faculty of Pharmacy,is provided to the patients and they are asked to apply this cream to the right side of their cheek once a day. Patients are followed up at intervals of 4, 8, and 12 weeks, and their recovery rate, satisfaction, and Masi score are checked for them. Thyroid function tests are also requested again in the 8th week. The side effects and recovery rate will be checked based on the

mentioned cases at the end of the 12th week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Dr Hamideh Herizchi-Ghadim

Street address

Maralan street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Hamideh Herizchi- Ghadim

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

dermatologist

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Position

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Person responsible for updating data

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The data of the study are classified and coded so that the names of the people cannot be identified.
When the data will become available and for how long
Access starts from the beginning of data collection November 1401
To whom data/document is available
For researchers in academic institutions
Under which criteria data/document could be used
In order to use in other studies
From where data/document is obtainable
To me, Hamida Harizchi Ghadim, all the ways of communication have been mentioned in the previous section Priority through phone call , Email and then SMS Shaghayegh Babapoor through phone call, SMS and E-mail
What processes are involved for a request to access data/document
After receiving the request via phone call or SMS and email, it will be sent within a week.
Comments