Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A comparative study of the efficacy of topical metformin cream versus placebo in the treatment of melisma

Protocol summary

Study aim
A comparative study of the efficacy of topical metformin cream versus placebo in the treatment of melisma
Design
In a four-phase clinical trial, 60 patients with melasma were studied in either the 15% metformin group or the placebo group. Patients were not aware of the type of drug. Also, the analyst did not know the type of drug
Settings and conduct
In a four-phase clinical trial, 60 patients with melasma referred to Dermatology Clinic of Ahvaz Imam Khomeini Hospital were studied in either the 15% metformin group or the placebo group. Medication or placebo was taken twice a day for three months. Patients were monitored on a monthly basis and MASI score was calculated and photographed before and at each visit.
Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients with melasma referred to Dermatology Clinic of Ahvaz Imam Khomeini Hospital Exclusion criteria: Patients who do not wish to continue treatment
Intervention groups
Intervention group: The 15% metformin cream was used twice a day for three months Control group: Placebo was used twice a day for three months
Main outcome variables
Improvement of MASI score

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20121104011363N3**
Registration date: **2019-01-14, 1397/10/24**
Registration timing: **retrospective**

Last update: **2019-01-14, 1397/10/24**
Update count: **0**
Registration date
2019-01-14, 1397/10/24

Registrant information
Name
Hannaneh Davoodzadeh
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-08-23, 1396/06/01
Expected recruitment end date
2019-03-16, 1397/12/25
Actual recruitment start date
2017-08-23, 1396/06/01
Actual recruitment end date
2018-12-14, 1397/09/23
Trial completion date
2018-12-14, 1397/09/23

Scientific title
A comparative study of the efficacy of topical metformin cream versus placebo in the treatment of melisma

Public title
A comparative study of the efficacy of topical metformin cream versus placebo in the treatment of melisma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

All patients with melasma referred to Dermatology Clinic of Ahvaz Imam Khomeini Hospital

Exclusion criteria:

Pregnancy Breastfeeding Patients receiving hormone therapy Atrophy and telangiectasia in the place of melasma Use of topical treatment for melasma in the last 3 months History of drug sensitivity GFR less than 30

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard, Ahvaz, Iran

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Province

Khouzestan

Postal code

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Approval date

2018-09-15, 1397/06/24

Ethics committee reference number

IR.AJUMS.REC.1397.391

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Improvement of MASI score

Timepoint

At the end of every month and 3 months after improvement

Method of measurement

MASI score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The 15% metformin cream was used twice a day for three months

Category

Treatment - Drugs

2

Description

Control group: Placebo was used twice a day for three months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Mohammad Ali Mapar

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Sponsors / Funding sources

1

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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
Ahvaz 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
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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
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
belong to the Ahvaz Jundishapur University of Medical Sciences opinion
When the data will become available and for how long
belong to the Ahvaz Jundishapur University of Medical Sciences opinion
To whom data/document is available
belong to the Ahvaz Jundishapur University of Medical Sciences opinion
Under which criteria data/document could be used
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From where data/document is obtainable
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What processes are involved for a request to access data/document
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Comments