

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1373 8255

Email address

davoodzadeh.h@ajums.ac.ir

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

City

Ahvaz

Province

Khouzestan

Postal code

1234567899

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

Street address

Ahvaz Imam Khomeini Hospital, Azadegan Ave.,
Ahvaz, Iran

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Email

src@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

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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**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Ghazal Namdari

Position

Student

Latest degree

Specialist

Other areas of specialty/work

Dermatologist

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Ali Mapar

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatologist

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Person responsible for updating data

Contact**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Hannaneh Davoodzadeh

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Jondi Shapour University of Medical Sciences of
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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

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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