Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the Efficacy of topical isoniazid versus placebo in the treatment of patients with melasma in a randomized double-blind clinical trial

Protocol summary

Study aim
Comparison of the Efficacy of topical isoniazid versus placebo in the treatment of patients with melasma in a randomized double-blind clinical trial

Design
The study is a double-blind,randomized clinical trial with control group and parallel group design

Settings and conduct
This is a randomized double-blind clinical trial study. 20 patients with age of between 20 and 60 years old with diagnosed melasma attending dermatology clinic in Afzalipour Hospital in Kerman enroll the study. Patients are allocated to 2 groups (intervention and control) . intervention group will recieve isonicotinic acid hydrazide 10% and control group will recieve cold cream.

Participants/Inclusion and exclusion criteria
The inclusion criteria include patients with diagnosed melasma with age of between 20 and 60 years old. The exclusion criteria include Other topical medication users for melasma in the last four weeks, Kubner-positive diseases such as vitiligo ,Lactation and pregnancy,Not consent to medical photography.

Intervention groups
patients in intervention group recieve isonicotinic acid hydrazide 10% by Exir factory (topical, once daily for 3months) and control group recieve cold cream by Gol daru factory (topical, once daily for 3months).

Main outcome variables
Melanin content, Erythema content, Local complications, Systemic complications, Efficacy percentage

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211125053175N1**
Registration date: **2022-01-29, 1400/11/09**
Registration timing: **prospective**

Last update: **2022-01-29, 1400/11/09**
Update count: **0**

Registration date
2022-01-29, 1400/11/09

Registrant information

Name
Zahra Mahmoudi Saleh abad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-08-23, 1401/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Efficacy of topical isoniazid versus placebo in the treatment of patients with melasma in a randomized double-blind clinical trial

Public title

Evaluating effectiveness of therapy with topical isoniazid in melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with minimum age 20 years old to maximum 60 years old Patients with diagnosed melasma

Exclusion criteria:

Other topical medication users for melasma in the last four weeks Kubner-positive diseases such as vitiligo Lactation and pregnancy Not consent to medical photography

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, a list of random numbers was created using Excel software that determined the patients in treatment groups. In this method, the presence of patients in groups was based on the inclusion in the study after obtaining informed consent. In this study, opaque sealed plates were used to conceal random allocation, so that it is not possible to guess the allocation of each patient to the treatment group until the envelope is opened.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study for patients and data analyzor . both drugs were kept in identical plastic containers,so the evaluating physician and patient didn't know about their containings.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical sciences

Street address

Ebne Sina Ave,Tahmasb Abad Blvd.

City

Kerman

Province

Kerman

Postal code

761614111

Approval date

2021-10-25, 1400/08/03

Ethics committee reference number

IR.KMU.AH.REC.1400.169

Health conditions studied

1

Description of health condition studied

melasma

ICD-10 code

L81.4

ICD-10 code description

Other melanin hyperpigmentation

Primary outcomes

1

Description

Melanin content

Timepoint

At the begining of the study (before intervention) and 4, 8 and12 weeks after intervention

Method of measurement

According to Quantitative measurement of erythema and pigmentation of the patient's skin by Swiss made Dermocatch device

2

Description

Efficacy

Timepoint

Percentage change in melanin content before intervention and 12 weeks after intervention.

Method of measurement

Quantitative measurement of pigmentation of the patient's skin by Swiss made Dermocatch device.

3

Description

Erythema content

Timepoint

At the begining of the study (before intervention) and 4, 8 and12 weeks after intervention

Method of measurement

Using Quantitative measurement of erythema and pigmentation of the patient's skin by Swiss made Dermocatch device

Secondary outcomes

1

Description
Erythema
Timepoint
At the begining of the study (before intervention) and 4, 8 and12 weeks after intervention
Method of measurement
By physical examination and classification of the complications severity into mild, moderate and severe

2

Description
Scaling
Timepoint
At the begining of the study (before intervention) and 4, 8 and12 weeks after intervention
Method of measurement
By physical examination and classification of the complications severity into mild, moderate and severe

3

Description
Burning sensation
Timepoint
At the begining of the study (before intervention) and 4, 8 and12 weeks after intervention
Method of measurement
By physical examination and classification of the complications severity into mild, moderate and severe

4

Description
Increased liver enzymes
Timepoint
At the begining of the study (before intervention) and 12 weeks after intervention
Method of measurement
Based on blood test findings

Intervention groups

1

Description
Intervention group:Isonicotinic acid hydrazide cream 10%. How to use: Topical use, once daily. Duration of treatment: 12 weeks. Manufacturing factory: Exir, Iran.
Category
Treatment - Drugs

2

Description
Control group: Intervention group: Cold cream. How to use: Topical use, every night. Duration of treatment: 12 weeks. Manufacturing factory:Gol daroo Pharmaceutical Factory.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital
Full name of responsible person
Rezvan Amiri
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Imam Highway, Afzalipour Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Rezvan Amiri
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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