

# 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 receive isonicotinic acid hydrazide 10% and control group will receive 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 receive isonicotinic acid hydrazide 10% by Exir factory (topical, once daily for 3months) and control group receive 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3132 8000

###### Email address

minamh1992@gmail.com

##### 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 analyzer . 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 beginning of the study (before intervention) and 4, 8 and 12 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 beginning of the study (before intervention) and 4, 8 and 12 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 beginning of the study (before intervention) and 4, 8 and 12 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 beginning 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

##### Street address

Imam Highway, Afzalipour Hospital

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913911

##### Phone

+98 34 3132 8328

##### Email

rezvanamiri1358@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Abbas Pardakhty

##### Street address

Ebne Sina Avenue, Jihad Blvd

##### City

Kerman

##### Province

Kerman

##### Postal code

7619813159

##### Phone

+98 34 3226 3855

##### Email

minamh1992@gmail.com

#### 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**

Dermatology

**Street address**

Imam Highway, Afzalipour Hospital

**City**

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kerman University of Medical Sciences

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**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Rezvan Amiri

**Position**

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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