

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Effect of metformin on outcomes of hyperglycemia, inflammatory markers, asthma control test (ACT) and spirometry in patients with concurrent asthma and metabolic syndrome

Protocol summary

Study aim

Effect of metformin on outcomes of hyperglycemia, inflammatory markers, asthma control test (ACT), and spirometry in patients with concurrent asthma and metabolic syndrome.

Design

A clinical trial with a control group, with parallel groups, double-blind. Randomization in two intervention and control groups as block randomization in blocks of 4 by using the sealed envelope website, phase 3 with a sample size of 110 samples, two study groups of 55 people.

Settings and conduct

Patients will receive standard treatment for severe asthma attacks based on random allocation using blockade treated with metformin 500 mg in the form of tablets or placebo of Pharmed Company with the same shape in Imam Khomeini Hospital in Sari. The drug will start by giving one pill on the first day and will increase to one pill twice a day on the third day. This dose will continue until the end of the three-month follow-up period. The study is two-sided blind and the patient and the nurse delivering the medicine in the internal ward and the evaluating physician do not know the type of medicine. Demographic and clinical characteristics of patients at the time of hospitalization and during serial visits to pulmonary and endocrine clinics of Touba Center will be recorded by a physician using a checklist containing information about patients.

Participants/inclusion and exclusion criteria

Inclusion criteria for all patients 18 years and older with severe asthma attack admitted to Imam Khomeini Hospital in Sari who also have metabolic syndrome at the same time.

Intervention groups

The intervention group includes people with asthma and metabolic syndrome at the same time, one group

receiving metformin and another group receiving placebo metformin.

Main outcome variables

Blood sugar, inflammatory markers, asthma control test, spirometry.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220305054199N1**

Registration date: **2022-11-01, 1401/08/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-01, 1401/08/10**

Update count: **0**

Registration date

2022-11-01, 1401/08/10

Registrant information

Name

Hosein Mehravaran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3337 3689

Email address

hmehravaran@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of metformin on outcomes of hyperglycemia, inflammatory markers, asthma control test (ACT) and spirometry in patients with concurrent asthma and metabolic syndrome

Public title

Effect of metformin in patients with concurrent asthma and metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with concurrent asthma and metabolic syndrome

Exclusion criteria:

Patients with COPD, hypercapnic respiratory failure, bronchiectasis and respiratory system cancers Patients with diabetes People at high risk of malnutrition Patients with renal failure with creatinine clearance less than 30 cc per minute Heart Failure class 4 Hemoglobinopathy includes thalassemia major and intermedia and sickle cell anemia severe liver failure Patient with severe sepsis Patient with cancer

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in intervention and control groups will be done as block randomization in blocks of 4 by using the sealed envelope website (online randomization website). The output of the software is A and B, one for intervention and the other one for control group. In this way, the samples are divided into two intervention and control groups. The second colleague communicates with the first colleague using central randomization based on the order in which the participants entered the study and asks about the random assignment of the participant to a specific group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Metformin or metformin placebo will be coded in sealed

envelopes by a project partner, other than the treating physician. Placebo is designed as pills that are similar in shape, size and color to the original Metformin drug.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

Sari Amir Mazandarani Ave, Emam Hospital

City

Sari

Province

Mazandaran

Postal code

4816633131

Approval date

2022-02-02, 1400/11/13

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1400.086

Health conditions studied**1****Description of health condition studied**

Asthma

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Metabolic Syndrome

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Capillary blood glucose concentration and HbA1C

Timepoint

Before meals and two hours after breakfast at the beginning of hospitalization and discharge and one and three months after discharge

Method of measurement

Using Pars Azmoon Kit

2

Description

The rate of asthma attacks leads to emergency room visits and hospitalization

Timepoint

At the time of hospitalization and one and three months after hospitalization

Method of measurement

Asthma control test (ACT) and spirometry and clinical history

3

Description

The rate of inflammatory markers

Timepoint

At the time of hospitalization and discharge and one and three months after discharge

Method of measurement

Measurement of C-reactive protein (CRP) levels

4

Description

HbA1C

Timepoint

At the time of hospitalization and one and three months after hospitalization

Method of measurement

Using Pars Azmoon Kit

Secondary outcomes

1

Description

Body mass index

Timepoint

At the beginning of hospitalization and one and three months after starting metformin

Method of measurement

By a doctor

Intervention groups

1

Description

Intervention group: Patients receiving standard treatment for severe asthma attacks, according to the GINA guideline, based on random allocation using blockade, are treated with metformin 500 mg in tablets. The drug will start by giving one pill on the first day and increase to one capsule twice a day on the third day. This dose will continue until the end of the three-month follow-up period.

Category

Treatment - Drugs

2

Description

Control group: According to the GINA guideline, patients receive standard treatment for severe asthma attacks based on random allocation using blockade treated with a Pharmed placebo in the same shape as metformin tablets. The placebo will start by giving one pill on the first day and increase to one capsule twice a day on the third day. This dose will continue until the end of the three-month follow-up period.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Seyed Hossein Mehravaran

Street address

Razi Street - Imam Khomeini Hospital

City

Sari

Province

Mazandaran

Postal code

۳۳۱۳۱ -۴۸۱۶۶

Phone

+98 11 3335 0670

Email

ravabetomoomi@mazums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Seyed Hossein Mehravaran

Street address

Sari, Imam Square, Joibar three ways, at the beginning of Valiasr Highway, Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 11 3304 4000

Email

ravabetomoomi@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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

4816633131

Phone

+98 11 3337 3689

Fax**Email**

hmehravaran@mazums.ac.ir

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

Mazandaran University of Medical Sciences

Full name of responsible person

Hosein Mehravaran

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Sari, AmirMazandarani Ave, Emam Hospital

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3337 3689

Fax**Email**

hmehravaran@mazums.ac.ir

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

Mazandaran University of Medical Sciences

Full name of responsible person

Hosein Mehravaran

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Sari, AmirMazandarani Ave, Emam Hospital

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3337 3689

Fax**Email**

hmehravaran@mazums.ac.ir

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

Mazandaran University of Medical Sciences

Full name of responsible person

Hosein Mehravaran

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Sari, AmirMazandarani Ave, Emam Hospital

City

Sari

Province

Mazandaran

Postal code**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

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

Due to the novelty of this study and the lack of other similar articles, for the sake of transparency of the study, the initial data of the project can be shared as an Excel file after de-identifying people.

When the data will become available and for how long

The data access period is six months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions can access the data.

Under which criteria data/document could be used

The use of these data in articles and scientific research is allowed.

From where data/document is obtainable

To receive the data, send an email to hmehravaran@mazums.ac.ir, which belongs to Dr. Hossein Mehravaran.

What processes are involved for a request to access**data/document**

After sending the applicant's personal details and scientific background and information related to the study, including the purpose of the study, it will be checked and if approved, the information will be provided to the person.

Comments