

# 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**