

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the effect of adding Trimetazidine to standard treatment of patients with Aluminum phosphide poisoning, referral to Loghman Hospital In Tehran, a pilot study on mortality

#### Protocol summary

##### Study aim

Determining the effect of adding Trimetazidine to standard treatment of Aluminum phosphide poisoning

##### Design

Clinical trial of control group drug with parallel, single-blind, randomized groups

##### Settings and conduct

In this study, 30 patients who were diagnosed with Aluminum phosphide poisoning and referred to Loghman poisoning center were included and were randomly divided into two groups of 15 by random allocation software. All patients were in the age group of 18-60 years who were poisoned with oral form and arrived at the emergency part of Loghman Hospital 24 hours before consuming rice pills. Inclusion criteria in addition to age group and time and history Taking rice aluminum phosphide and clinical signs, silver nitrate test Positive or negative or silver nitrate test is positive in the absence of the above clinical symptoms or in the absence of clinical symptoms, their carbon monoxide test is higher than 10 if not smoking.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1-Poisoning with oral form of Aluminum Phosphide tablets and referring to medical centers before 24 hours 2- Age range 18 to 60 years 3-Clinical signs based on phosphide aluminum tablet poisoning 4- Positive silver nitrate test of oral and gastric secretions 5-Carbon monoxide levels above 10 in non-smokers  
Exclusion Criteria: 1-Renal glomerular filtration rate less than 30 on arrival 2-Known heart failure and a history of acute myocardial infarction 3-Pregnant and lactating women 4- Concomitant use of drugs such as methadone, tricyclic antidepressants and amphetamines

##### Intervention groups

Patients with Aluminum phosphide poisoning are divided into two groups of 15 people with standard treatment +Trimetazidine group and standard treatment group.

#### Main outcome variables

Hospital mortality, need for ICU, intubation,

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211017052794N1**

Registration date: **2022-04-13, 1401/01/24**

Registration timing: **prospective**

Last update: **2022-04-13, 1401/01/24**

Update count: **0**

##### Registration date

2022-04-13, 1401/01/24

##### Registrant information

##### Name

Zohreh Mansourian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2243 2273

##### Email address

a.mansoriyan@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-22, 1401/06/31

##### Expected recruitment end date

2023-01-19, 1401/10/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effect of adding Trimetazidine to standard treatment of patients with Aluminum phosphide poisoning, referral to Loghman Hospital In Tehran, a pilot study on mortality

**Public title**  
Investigation of the effect of Trimetazidine in patients with Aluminum phosphide poisoning

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Consumption of oral form of Aluminium phosphide and refers to Loghman Hospital under 24 hours and the presence of symptoms consistent with poisoning Positive silver nitrate test Carbon monoxide levels above 10 in non-smokers  
**Exclusion criteria:**  
Glomerular Filtration Rate(GFR) less than 30 (if available ),history of renal failure , history of liver failure , history of acute myocardial infarction, history of heart failure, history of congenital heart disease Pregnancy and lactation Refer to hospital after 24 hours

**Age**  
From **18 years** old to **60 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this research, block random sampling method will be used. In the present study, 2 groups are studied (intervention group and control group) Therefore, quadruple blocks will be used. According to the calculated sample size (total number of 30 people who are divided into two groups of 15 people). 8 quadruple blocks will be considered. Random assignment of individuals to the groups under study will be done in this way. First, 15 envelopes containing four cards with A, B, C, D Latin letters were prepared, letters A and B = intervention group, letters C and D = as control group. According to the inclusion criteria, they were asked to The 30 sealed envelopes randomly selected one and randomly selected a card from within that the card label determined the assignment of the individual to each of the two study groups.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
In this study, patients are unaware of the drug allocation,

in fact, the patient does not know whether he is receiving Trimetazidine in addition to standard treatment or only under standard treatment. Before starting the drug. Explain to each patient or their first-degree family Will be given to enter a clinical trial study with written consent and informed consent. The nurses responsible for administering the medication are in the process of designing the study but are unaware of the interventions and objectives under study but Internal medicine specialists, toxicologists and cardiologists are aware of this issue.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Beheshti University of Medical Sciences

##### Street address

Velenjak - Daneshjoo Boulevard - Shahid Beheshti Faculty of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2022-03-11, 1400/12/20

#### Ethics committee reference number

IR.SBMU.MSP.REC.1400.783

## Health conditions studied

### 1

#### Description of health condition studied

Patients with Aluminum phosphide poisoning

#### ICD-10 code

T50.901

#### ICD-10 code description

Poisoning by unspecified drugs, medicaments and biological substances, accidental (unintentional)

## Primary outcomes

### 1

#### Description

Mortality

#### Timepoint

During hospitalization

## Method of measurement

Death during admission

## Secondary outcomes

### 1

#### Description

Admit duration

#### Timepoint

Period of time

#### Method of measurement

Daily chart

### 2

#### Description

Icu admission

#### Timepoint

Number of hospitalization days

#### Method of measurement

Daily chart

### 3

#### Description

Arrhythmia

#### Timepoint

Daily electrocardiogram/As long as the patient is being treated with trimetazidine

#### Method of measurement

Electrocardiogram

### 4

#### Description

Need for inotropic drugs

#### Timepoint

Number of hospitalization days

#### Method of measurement

Based on blood pressure less than 90 mmHg and inotrop drugs initiation recorded in the chart

### 5

#### Description

Left ventricle ejection fraction

#### Timepoint

Second day of admission

#### Method of measurement

Echocardiography

### 6

#### Description

Intubation

#### Timepoint

Hospital admission

#### Method of measurement

Number of intubation patients registered in the chart

## Intervention groups

### 1

#### Description

Biogaran tablets with the chemical composition of Trimetazidine, 35 mg, which is used orally every 12 hours for 5 days. This drug is made by the French company Biogaran. During this 5-day period and other days of hospitalization, patients are closely monitored and all variables are checked and charted.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: In this group of 15 patients, the identified patients are treated with Trimetazidine 35 mg tablet from Biogaran Pharmaceutical Company for 5 days, every 12 hours, and during this period of 5 days and other days of hospitalization, the desired variables are monitored and examined and the information is charted.

#### Category

Treatment - Drugs

### 3

#### Description

Control group: In this group of 15 patients, all patients receive only standard treatment while hospitalized and are not treated with Trimetazidine tablets.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Loghman Hakim Hospital

##### Full name of responsible person

Mehdi Sheibani

##### Street address

South Kargar Street

##### City

Tehran

##### Province

Tehran

##### Postal code

1333625445

##### Phone

+98 21 5102 5291

##### Email

a.mansouriyan@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mehdi Sheibani

**Street address**

Erabi street-Velenjak

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a.mansoriyan@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mehdi Sheibani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Cardiology

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### Person responsible for scientific inquiries

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### Person responsible for updating data

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Zohreh Mansourian

**Position**

Internal resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

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**Province**

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**Phone**

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**Email**

a.mansoriyan@gmail.com

### 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**

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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The results of the study will be published as a scientific article

**When the data will become available and for how**

**long**

Access will be available after the article is published

**To whom data/document is available**

Reputable scientific and research centers

**Under which criteria data/document could be used**

For further studies

**From where data/document is obtainable**

By email to the person in charge of the research project

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

No specific process is considered

**Comments**