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,referal 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 phosohide 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

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Iran (Islamic Republic of)

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+98 21 2243 2273

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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,referal 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 referrs 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
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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
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
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Position
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Person responsible for updating data

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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
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