

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparing therapeutic effects of sodium bicarbonate with magnesium sulfate in moderate and severe acute organophosphorous pesticide poisoning.

Protocol summary

Summary

Comparing therapeutic effects of sodium bicarbonate, magnesium sulfate, both and none of them in moderate and severe acute organophosphorous pesticide poisoning. Objectives: This trial is held in developing a more effective treatment regimen for acute organophosphorous poisoning. Design: This is a double-blind, parallel-group study on a total target sample size of 120 patients aged 14 to 65 years old with moderate and severe acute organophosphorous pesticide poisoning. Setting and conduct: Based on the two last digits of their dossiers' number, all eligible participants will be assigned into 4 parallel groups in 1:1:1:1 ratio to receive either one of the 3 supplementary regimens in three intervention groups or merely the conventional treatment in a no supplementary treatment control group. Major inclusion criteria: All patients aged 14 to 65 years old with moderate to severe acute organophosphorous pesticide poisoning referring to Imam Reza Hospital, Mashhad, Iran, will enter the study followed by obtaining an informed consent. Major exclusion criteria: Evidence of heart and kidney dysfunction and magnesium intoxication will be considered as exclusion criteria. Intervention: All patients will receive the conventional treatment; besides, they will receive intravenous infusion of sodium bicarbonate 7.5% for the first 3 days of hospitalization, aiming at arterial pH between 7.45 and 7.55 (first study group), intravenous infusion of magnesium sulfate 20% in the very beginning of admission (second study group), intravenous infusion of both above-mentioned supplementary treatments (third study group). Main outcome measures: Ultimately, based on their dossier's notes, the principle researcher will inspect variables including the dosage of Atropine administered for patients' Atropinization, hospitalization duration, the necessity to Intensive Care Unit, the necessity to

mechanical ventilation, the necessity to Benzodiazepines, seizure incidence and their final clinical outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803031187N2**

Registration date: **2014-12-17, 1393/09/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-17, 1393/09/26

Registrant information

Name

Reza Afshari

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 8973

Email address

afsharir@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2008-06-21, 1387/04/01

Expected recruitment end date

2009-09-21, 1388/06/30

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparing therapeutic effects of sodium bicarbonate with magnesium sulfate in moderate and severe acute organophosphorous pesticide poisoning.

Public title

Studying administration of sodium bicarbonate and magnesium sulfate in clinical betterment of acute organophosphorous pesticide poisoning.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients aged 14 to 65 years old with moderate and severe acute organophosphorous pesticide poisoning referring to Imam Reza Hospital, Mashhad, Iran who or whose guardian has confirmed the relevant informed consent. Exclusion criteria: Any evidence of conductive heart diseases and myocardial injuries (inspected by Electrocardiography and plasma Troponin, every 12 hours respectively); renal dysfunction (less than 100 ML urine output for every 4 hours); concurrent administration of Digitals or Central Nervous System suppressors or Neuromuscular Junction blockers (through patients' drug history); any manifestation of magnesium intoxication (through physical examination every 2 hours while administering magnesium sulfate).

Age

From **14 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

All patients who meet our including criteria, regardless of whether they will be put into the control or study groups, will be asked to confirm the informed consent. Besides, the principle researcher who is responsible for investigating the study's variables is totally different from the therapists who allocate the patients into the four groups, based on the two last digit of their dossiers' number (randomized numbers chart) , resulting in the project being double blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University Ethics Committee, Mashhad University of Medical Sciences (MUMS)

Street address

Mashhad University of Medical Sciences central office, Daneshgah St.

City

Mashhad

Postal code

91375-345

Approval date

2007-02-13, 1385/11/24

Ethics committee reference number

84386

Health conditions studied

1

Description of health condition studied

Moderate and severe acute Organophosphorous pesticide poisoning

ICD-10 code

T60.0

ICD-10 code description

Organophosphorous and Carbamate insecticides

Primary outcomes

1

Description

The dosage of Atropine administered for patients' Atropinization

Timepoint

In the first day of admission

Method of measurement

In scale of milligrams and according to the notes of patients' dossiers

2

Description

Hospitalization duration

Timepoint

At the end of hospitalization

Method of measurement

In scale of days and according to the notes of patients' dossiers

3

Description

Necessity to the Intensive Care Unit
Timepoint
Every morning and at the end of hospitalization
Method of measurement
According to the notes of patients' dossiers

4

Description
Necessity to mechanical ventilation
Timepoint
Every morning and at the end of hospitalization
Method of measurement
According to the notes of patients' dossiers

5

Description
Necessity to administrating Benzodiazepines
Timepoint
Every 12 hours and at the end of hospitalization
Method of measurement
According to the notes of patients' dossiers

6

Description
Seizure incidence
Timepoint
Every day and at the end of hospitalization
Method of measurement
According to the notes of patients' dossiers

7

Description
Patients' outcome
Timepoint
At the end of hospitalization
Method of measurement
According to the notes of patients' dossiers, based on whether discharged with no organophosphorous poisoning complications, discharged with some organophosphorous poisoning complications and death

Secondary outcomes

1

Description
Arterial blood pH
Timepoint
Every 12 hours
Method of measurement
Arterial blood pH measurement by pH meter

Intervention groups

1

Description
First intervention group: Intravenous infusion of 6 to 12

Sodium Bicarbonate (Pasteur Institute) 7.5% 50 ML Bags in every 24 hours for the first 3 days of hospitalization, aiming at arterial pH between 7.45 and 7.55.

Category
Treatment - Drugs

2

Description
Second intervention group: Intravenous infusion of Magnesium Sulfate (Samen Corporation) 20% 10 ML Vial, 4 grams in 4 hours, in the very beginning of admission.
Category
Treatment - Drugs

3

Description
Third intervention group: Intravenous infusion of 6 to 12 Sodium Bicarbonate (Pasteur Institute) 7.5% 50 ML Bags in every 24 hours for the first 3 days of hospitalization, aiming at arterial pH between 7.45 and 7.55 and intravenous infusion of Magnesium Sulfate (Samen Corporation) 20% 10 ML Vial, 4 grams in 4 hours, in the very beginning of admission.
Category
Treatment - Drugs

4

Description
Control (forth) group: Merely the conventional treatment. No supplementary treatment.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Toxicology ward, Medical Toxicology Centre and Addiction Research Center, Imam Reza Hospital
Full name of responsible person
Seyedmahyar Mohammadi
Street address
Imam Reza SQ., Ebn-e Sina St.
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Sciences (MUMS)
Full name of responsible person
Mahyar Mirheydari, MD
Street address

Mashhad University of Medical Sciences central office,
Daneshgah St.

City

Mashhad

Grant name

طرح تحقیقاتی دانشگاه

Grant code / Reference number

84386

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

Yes

Title of funding source

Vice Chancellor for Research, Mashhad University of
Medical Sciences (MUMS)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Medical Toxicology Center and Addiction Research
Center, Mashhad University of Medical Sciences

Full name of responsible person

Reza afshari, M.D.

Position

Clinical toxicologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Seyedmahyar Mohammadi

Position

General Practice intern

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty