

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of therapeutic effects of Magnesium Sulfate (MgSO₄) in acute organophosphate pesticide poisoning

Protocol summary

Summary

Cases will be selected among moderate to severe organophosphate poisoned patients who are recruited to Medical Toxicology Ward of Imam Reza Hospital, Mashhad, Iran and will be divided in to two groups: study and Control group. Standard organophosphate poisoning treatment (atropine and oxime) will begin for both groups. More intensive supportive cares will be done in accordance with the physician's discretion. Blood samples will be given for Acetyl cholinesterase and butyryl cholinesterase assays, as well as hematologic and biochemical assays. In the case group, MgSO₄.7H₂O 20% will be administered in divided doses of 4 grms within intervals of 4 hours with the maximum of 16 grm in the first day. Equivalent patient in control group will receive the same number and volume of normal saline infusion as placebo. Mg level will be measured before the first infusion and will be continued daily. 24 hour urine collection will be done in order to Mg measurement. All the vital signs, physical examination and laboratory data and received doses of all the drugs will be recorded in predesigned forms. At last, the result of treatment will be recorded as total healing, healing with complications or death. Patients who reach normal cholinesterase levels and are also cholinergic symptoms free, will be known as complete healed patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104272083N3**

Registration date: **2014-08-04, 1393/05/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-04, 1393/05/13

Registrant information

Name

Seyed Reza Mousavi

Name of organization / entity

Imam Reza Hospital, Mashhad University of Medical science

Country

Iran (Islamic Republic of)

Phone

+98 51 1859 8973

Email address

mousavir@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences, Mashhad, Iran

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effects of Magnesium Sulfate (MgSO₄) in acute organophosphate pesticide poisoning

Public title

Therapeutic effects of Magnesium Sulfate (MgSO₄) in acute organophosphate pesticide poisoning

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Determined acute moderate to severe organophosphate poisoning ; filling the written informed consent by the patients or close relatives in cases with diminished consciousness. Exclusion criteria: disinclination to continue ; age of below 10 years or above 60 years old; mild organophosphate poisoning ; history of severe diseases such as heart, lung,renal or hepatic insufficiency, and metabolic diseases ; simultaneous poisoning with other chemicals ; history of epilepsy prior to the poisoning ; passing more than 24 hours after the consumption ; occurring of primary signs and symptoms of Mg poisoning in case group ; ECG changes that require different dose of MgSO4 administration or any other interfering drug

Age

From **10 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research department, Mashhad University of Medical Sciences, Mashhad, Iran

Street address

2nd floor, central building of Mashhad University of Medical Sciences (Ghorshi building), Daneshgah avenue, Mashhad, Iran

City

Mashhad

Postal code**Approval date**

2014-01-11, 1392/10/21

Ethics committee reference number

921143

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

Acute organophosphate pesticide posoning

ICD-10 code

T60.0

ICD-10 code description

Organophosphate and carbamate insecticides

Primary outcomes**1****Description**

RBC Cholinesterase level

Timepoint

prior to the treatment and daily

Method of measurement

blood sample

2**Description**

ICU admission

Timepoint

after the intervention

Method of measurement

Number of days during ICU admission

3**Description**

mechanical ventilation

Timepoint

after the intervention

Method of measurement

number of days within the patient needs mechanical ventilation

4**Description**

patients' mortality

Timepoint

after the intervention

Method of measurement

observation

5**Description**

post-loading maintenance doses of atropine

Timepoint

at the beginning and at the end of patient's admission

Method of measurement

sum of maintenance of atropine in each day of admission (mg)

Secondary outcomes

1

Description

hypotension as a complication of MgSO₄ infusion

Timepoint

continuously from the beginning of the infusion

Method of measurement

cardiac monitoring

2

Description

diminished respiratory rate as a complication of MgSO₄ infusion

Timepoint

continuously from the beginning of the infusion

Method of measurement

cardiac monitoring

3

Description

diminished deep tendon reflexes as a complication of MgSO₄ infusion

Timepoint

each 5 minutes from the beginning of the infusion

Method of measurement

physical examination

Intervention groups

1

Description

MgSO₄.7H₂O 20% will administer in divided doses of 4 grms with interval of 4 hours with the maximum of 16 grm. MgSO₄ will be administered as infusion with 250 cc of normal saline within 20 minutes

Category

Treatment - Drugs

2

Description

290 cc normal saline will be infused within 20 minutes in control group, in accordance with number and time interval of infusions in intervention group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Medical Toxicology Research Center (MTRC)

Full name of responsible person

Dr. Seyed Reza Mousavi

Street address

Mashhad, Imam Reza Hospital

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research- Mashhad University of Medical Sciences, Mashhad, Iran

Full name of responsible person

Dr. Tafaghodi

Street address

Research Department (Ghoreyshi building) - 2nd floor
- Daneshgah Avenue

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for research- Mashhad University of Medical Sciences, Mashhad, Iran

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 Research Center (MTRC)

Full name of responsible person

Seyed Reza Mousavi

Position

Assistant professor of Medical Toxicology

Other areas of specialty/work

Street address

Imam Reza Hospital, Medical Toxicology Research Center (MTRC)

City

Mashhad

Postal code

Phone

+98 51 1859 8973

Fax

+98 80 02467

Email

mousavir@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Meical Toxicology Research Center (MTRC)

Full name of responsible person

Dr. Mahdi Balali-Mood

Position

MD - PhD. in Clinical Pharmacology and Toxicology

Other areas of specialty/work

Street address

Imam Reza Hospital, Meical Toxicology Research Center (MTRC)

City

Mashhad

Postal code

Phone

+98 51 1859 8973

Fax

+98 80 02467

Email

balalimoodm@mums.ac.ir mbalalimood@hotmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Medical Toxicology Research Center (MTRC)

Full name of responsible person

Seyed Reza Mosavi

Position

Assistant professor of clinical toxicology

Other areas of specialty/work

Street address

Imam Reza Hospital, Medical Toxicology Research Center (MTRC)

City

Mashhad

Postal code

Phone

+98 51 1859 8973

Fax

+98 80 02467

Email

mousavir@mums.ac.ir

Web page address

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