

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Clinical trial of comparison of magnesium sulfate and placebo as supplement to standard treatment in patients with organophosphorus poisoning.

Protocol summary

Summary

Objectives: Clinical trial of comparison of magnesium sulfate and placebo as supplement to standard treatment in patients with organophosphorus poisoning. **Design and setting:** A randomized, double-blind, clinical trial study, single center, clinical trial phase 3, 80 Samples selected via patients with poisoning referred to the emergency of Valiasr and Amirmomenin Hospitals of Arak in 15 months and block randomized into two groups. **Inclusion criteria:** Age 18 to 65 years old; Taking time less than 2 hours after poisoning. **Exclusion criteria:** Concomitant use of drugs or other substance accidentally or as a suicidal attempt; History of severe complications or sensitivity to Magnesium sulfate. **Interventions:** Intervention group receives, Magnesium sulfate 50% at a dose of 2 grams bolus infusion for 30 minutes plus routine treatment, followed by the same dose infusion every 2 hours up to 3 doses. Control group receives placebo (normal saline) as same volume of magnesium sulfate added to routine treatment. **Main outcome measures:** Serum level of electrolytes, blood sugar, kidney and liver function tests, arterial blood gasses, size of pupils, deep tendon reflexes, fasciculation severity, respiratory crackle, salivary secretions and in case of intubation, tracheal secretions record every 30 minutes after each injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092823552N10**
Registration date: **2016-11-07, 1395/08/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-07, 1395/08/17

Registrant information

Name

Abolfazl Jokar

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 2134

Email address

dr.a.jokar@gmail.com

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2016-10-17, 1395/07/26

Expected recruitment end date

2018-01-16, 1396/10/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of magnesium sulfate and placebo as supplement to standard treatment in patients with organophosphorus poisoning.

Public title

Effect of Magnesium sulfate in organophosphorus poisoning

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 to 65 years old; patients with acute organophosphorus poisoning who do not receive medical care in another medical center; Taking time less than 2 hours after poisoning; Patients satisfaction.

Exclusion criteria: Unwillingness to participate in the study; Concomitant use of drugs or other substance accidentally or as a suicidal attempt; History of severe complications or sensitivity to Magnesium sulfate; History of heart block, Myocardial infarction, severe renal failure, Hepatitis and Addison's disease; Patients death.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study the randomization was conducted with block randomization method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University Of Medical Science, Basij Square, Arak

City

Arak

Postal code

Approval date

2016-10-17, 1395/07/26

Ethics committee reference number

IR.ARAKMU.REC.1395.260

Health conditions studied

1

Description of health condition studied

organophosphorus poisoning

ICD-10 code

T44

ICD-10 code description

Poisoning by drugs primarily affecting the autonomic nervous system

2

Description of health condition studied

organophosphorus poisoning

ICD-10 code

T60.0

ICD-10 code description

Organophosphate and carbamate insecticides

Primary outcomes

1

Description

tracheal secretions

Timepoint

every 30 minutes after each injection

Method of measurement

Physical examination

2

Description

respiratory crackle

Timepoint

every 30 minutes after each injection

Method of measurement

Physical examination

3

Description

Size of pupils

Timepoint

every 30 minutes after each injection

Method of measurement

Physical examination

4

Description

deep tendon reflexes

Timepoint

every 30 minutes after each injection

Method of measurement

Physical examination

5

Description

salivary secretions

Timepoint

every 30 minutes after each injection

Method of measurement

Physical examination

6**Description**

fasciculation severity

Timepoint

every 30 minutes after each injection

Method of measurement

Physical examination

Secondary outcomes**1****Description**

Liver function test

Timepoint

every 30 minutes after each injection

Method of measurement

Blood test

2**Description**

Blood urea nitrogen

Timepoint

every 30 minutes after each injection

Method of measurement

Blood test

3**Description**

creatinine

Timepoint

every 30 minutes after each injection

Method of measurement

Blood test

4**Description**

Serum level of electrolytes

Timepoint

every 30 minutes after each injection

Method of measurement

Blood test

5**Description**

Blood sugar

Timepoint

every 30 minutes after each injection

Method of measurement

Blood test

6**Description**

Arterial blood gasses

Timepoint

every 30 minutes after each injection

Method of measurement

Blood test

Intervention groups**1****Description**

Intervention group receive, Magnesium sulfate 50% at a dose of 2 grams bolus infusion for 30 minutes plus routine treatment, followed by the same dose infusion every 2 hours up to 3 doses.

Category

Treatment - Drugs

2**Description**

Control group receive placebo (normal saline) as same volume of magnesium sulfate added to routine treatment.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Vali-e-Asr hospital

Full name of responsible person

Abolfazl Jokar

Street address

Vali-e-Asr hospital, Vali-e-Asr square, Arak, Iran

City

Arak

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Dr. Mohammad Rafiee

Street address

Arak University of Medical Sciences, Basij Square, Arak, Iran

City

Arak

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

Yes

Title of funding source

Arak University of Medical Sciences, Vice Chancellor for

Research
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
Vali-e-Asr hospital
Full name of responsible person
Dr Abolfazl Jokar
Position
Emergency medicine specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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