

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of continuous infusion versus intermittent bolus injection of Pralidoxime for the treatment of Organophosphate poisoning

Protocol summary

Study aim

The aim of this study is to compare continuous infusion versus intermittent bolus injection of pralidoxime for the treatment of organophosphate poisoning

Design

Two arm parallel groups randomized trial with single blinding

Settings and conduct

Emergency Department of Ali-Asghar Hospital. The patients will be blinded from study interventions

Participants/Inclusion and exclusion criteria

Patients aged between 18 to 60 years with organophosphate poisoning admitted to the emergency department of Ali-Asghar Hospital. Exclusion criteria include patients who are poisoned with carbamate compounds, patients who have received treatment prior to arriving at our center, and patients with history of other pre-existing comorbid conditions and history of lung disease

Intervention groups

The patients will be randomized into two study groups. At first, all patients will be received IV bolus 1-2g/20min Pralidoxime as loading dose, then will be repeated every 6 hours for the patients in the group I, while the patients in the group II will be administered 8g/24 hours Pralidoxime by continuous infusion.

Main outcome variables

The primary outcomes are duration of atropine therapy, and duration of ICU stay. In addition, we will be considered mortality rate as secondary outcome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180613040087N1**

Registration date: **2018-08-01, 1397/05/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-01, 1397/05/10**

Update count: **0**

Registration date

2018-08-01, 1397/05/10

Registrant information

Name

Azadeh Tafakori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3822 9856

Email address

tafakori@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of continuous infusion versus intermittent bolus injection of Pralidoxime for the treatment of Organophosphate poisoning

Public title

Treatment of Organophosphate poisoning with Pralidoxime

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
 Patients with Organophosphate poisoning admitted to the emergency department of Ali-Asghar Hospital

Exclusion criteria:
 Patients with age less than 18 or more than 80 years old
 Patients who are poisoned with Carbamate compounds
 Patients who have received treatment prior to arriving at our center
 Patients with history of history of lung diseases

Age
 From **18 years** old to **80 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant

Sample size
 Target sample size: **80**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization will be performed by using a randomization table based on the registration number of the patients.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 Just patients will be blinded to the intervention allocation.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Headquarters Of Shiraz University of Medical Sciences, Zand St, Shiraz

City

Shiraz

Province

Fars

Postal code

1456946111

Approval date

2018-06-18, 1397/03/28

Ethics committee reference number

IR.SUMS.MED.REC.1397.147

Health conditions studied

1

Description of health condition studied

Organophosphate poisoning

ICD-10 code

T60.0

ICD-10 code description

Toxic effect of organophosphate and carbamate insecticides

Primary outcomes

1

Description

Duration of Atropine therapy

Timepoint

From admission to hospital discharge

Method of measurement

Based on day

2

Description

Duration of ICU stay

Timepoint

From admission to hospital discharge

Method of measurement

Based on day

Secondary outcomes

1

Description

Mortality rate

Timepoint

From admission to hospital discharge

Method of measurement

Census

Intervention groups

1

Description

Intervention group: Continuous infusion of 8g pralidoxime in 24 hours

Category

Treatment - Drugs

2

Description

Intervention group: Bolus injection of 1-2g pralidoxime in 20 minutes, then will be repeated every 6 hours

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-Asghar Hospital

Full name of responsible person

Azadeh Tafakori

Street address

Emergency Department of Ali-Asghar Hospital,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Baser Hashemi

Street address

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Hasani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

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Position

Assistant professor

Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data related to the patients will be shared after identifying the patients.

When the data will become available and for how long

Starting 1 month after publication

To whom data/document is available

This only available for people working in academic institutions

Under which criteria data/document could be used

All statistical analysis are allowed in line with the objectives of the study. Application terms for access to data including: People working in academic institutions who have registered a protocol liked our study. People are committed to data protection.

From where data/document is obtainable

Azadeh Tafakori, Shiraz Nemazee Hospital, Email: dr.azadeh.tafakori@gmail.com

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

Through automation correspondence or email

Comments