

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Study of the efficacy of pralidoxime in the treatment of organophosphorus poisoning

Protocol summary

Study aim

The aim of study is determining the efficacy of pralidoxime in the treatment of organophosphorus poisoning patients

Design

In this study, based on simple randomization method, patients are divided into two groups of intervention and control group. In this study, 86 patients will be selected based on the statistics of registered patients last year, and this number is divided into two groups of 46 people based on simple randomization method. It should be noted that this work is done in phase 3.

Settings and conduct

86 patients are selected from the organophosphorus poisoning patients at Sina Hospital, Tabriz, randomly assigned to the two main groups and control groups, and receive the medication according to the instructions. Patients in the two groups were compared in terms of mortality, length of hospital stay, duration of mechanical intubation and ventilation, and distance between poisoning and mortality.

Participants/Inclusion and exclusion criteria

Patients (>12 yrs) poisoned with a special group of organophosphates entered to study. Non-organophosphorus and pregnant patients were excluded from the study.

Intervention groups

It includes 43 control groups who receive 2 mg intravenously atropine during treatment with atropine, then 2 mg every 5 to 10 minutes until atropine begins to work, and 43 main groups are treated with atropine and pralidoxime concomitantly. They receive 30 mg per kilogram of intravenous weight and then 8 to 10 mg per kilogram of body weight per infusion per hour.

Main outcome variables

Mortality Survey; Investigating the duration of mechanical intubation and ventilation; Investigation of the distance between poisoning and mortality; Investigating patients' need for oxygen therapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170609034406N5**

Registration date: **2020-07-06, 1399/04/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-06, 1399/04/16**

Update count: **0**

Registration date

2020-07-06, 1399/04/16

Registrant information

Name

Afshin Gharekhani

Name of organization / entity

Faculty of Pharmacy/Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2020-12-30, 1399/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the efficacy of pralidoxime in the treatment of organophosphorus poisoning

Public title

Efficacy of pralidoxime in the treatment of organophosphorus poisoning

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 12 years poisoning with a specific type of organophosphate similar patients in terms of severity of toxicity Not receiving pralidoxime before arrive hospital

Exclusion criteria:

Non-organophosphorous toxicity Pregnancy

Age

From **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random randomization is performed by creating random numbers between 10 and 90 by the computer. For numbers less than 45 and 45 people enter the control group and for numbers less than 45 people enter the intervention group. It should be noted that all patients will randomly enter the control or intervention group after selecting to enter the study by assigning a random number generated by the computer.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

None

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of medical Sciences

Street address

Center of Research and Technology - No 2 Central Building - Tabriz University of Medical Sciences -

golghasht Street - Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2018-12-24, 1397/10/03

Ethics committee reference number

IR.TBZMED.REC.1397.768

Health conditions studied

1

Description of health condition studied

Orghanophosphate poisonous patients

ICD-10 code

T60.0

ICD-10 code description

Toxic effect of organophosphate and carbamate insecticides

Primary outcomes

1

Description

Serum level of acetylcholinesterase enzyme

Timepoint

Daily measurement of serum acetylcholinesterase until the patient's day off

Method of measurement

ELISA kit

2

Description

Investigating the need for oxygen therapy in two groups including control and intervention.

Timepoint

Momentary monitoring of the patient to assess the need for oxygen therapy.

Method of measurement

Using the pulse oximeter device.

3

Description

Investigating the need for intubation and the duration of intubation in the two groups of control and intervention.

Timepoint

Using checklist to record the time of initiation and duration of intubation in patients with indication for intubation using data extracted from the patients medical files

Method of measurement

Already designed checklist for recording the time

4

Description

Investigating the need for mechanical ventilation and the duration of mechanical ventilation in two groups of control and intervention.

Timepoint

Using checklist to record the time of mechanical ventilation and duration of mechanical ventilation in patients with indication for mechanical ventilation using data extracted from the patients medical files

Method of measurement

According to criteria exist for mechanical ventilation, the time of initiation and the time spent on mechanical ventilation for each patients will be recorded using data extracted from patients medical files

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 43 patients selected by simple random, concomitant treatment with atropine (0.5 mg / ml, Daropaksh Company) (initial dose of 1-6 mg, which will be repeated every 3-5 minutes if necessary. Double the application will be applied) and pralidexime (2% of SERB) (loading dose 30 mg / kg and up to a maximum dose of 2000, then a maintenance dose of 8-10 mg / kg / h to a maximum of 650 mg / h).

Category

Treatment - Drugs

2

Description

Control group: 43 randomly selected patients, only receive atropine (0.5 mg / ml, Daropaksh Company) with initial dose of 1-6 mg, that will be repeated every 3-5 minutes if necessary. Dose will doubled if no response reported.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Afshin Gharekhani

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Sina Medical Research and Training Hospital Shahid Montazeri and Hafez squares Azadi Street Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Abolghasem Jouyban

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Drug Applied Research Center Medical Research and Development Complex Daneshgah St Tabriz Iran

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Grant name

Grant code / Reference number

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

No

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Afshin Gharekhani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available