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

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Afshin Gharekhani

Name of organization / entity
Faculty of Pharmacy/Tabriz University of Medical Sciences

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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 orghanophosphate similar patients in terms of severity of toxicity Not receiving pralidoxime before arrive hospital

Exclusion criteria:
Non-orghanophosphorous 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 Centeral 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, Daropakhsh 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, Darupakhsh 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

Street address
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
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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
Threre 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