Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Nov 2026

Evaluation of the efficacy of plasmapheresis in comparison with conventional treatment on electrolyte and coagulation parameters in patients poisoned with aluminum phosphide

Protocol summary

Study aim
Determining the efficacy of plasmapheresis in the treatment and outcome of patients poisoned with aluminum phosphide

Design
Non-randomized, Controlled, Single-blinding clinical trial, with the parallel groups, Phase 2-3 on 60 patients

Settings and conduct
In this study, 60 patients with aluminum phosphide poisoning from the poisoning ward of Khorshid hospital in Isfahan will be included in the study and will be randomly divided into two groups. In one group only the routine treatment will be used and in the second group in addition to the routine treatment, plasmapheresis will be used. Given the single-blinding of this study, the specialist and the patient are aware of the type of intervention, but the person who examines the patient and the data analyzer will not be aware of the type of intervention received by each group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: aluminum phosphide poisoning, aged between 20 and 65 years, patient/attendant consent to participate in the study. Non-inclusion criteria: any risk of coagulation disorders, a history of chronic renal failure.

Intervention groups
Control group: Patients in this group will receive only routine treatment. Continuous injection of normal saline and dopamine will be done along with olive oil gavage. In addition, intravenous administration of vitamin C, notch (NAC), magnesium sulfate, and calcium gluconate will be performed according to the usual protocol. Intervention group: Patients in this group will undergo plasmapheresis in addition to routine treatment mentioned in the control group.

Main outcome variables
Systolic blood pressure; Diastolic blood pressure; Creatinine; Sodium; potassium; Platelets

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200507047344N2**
Registration date: **2020-12-05, 1399/09/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-05, 1399/09/15**
Update count: **0**

Registration date
2020-12-05, 1399/09/15

Registrant information
Name
shafeajafar zoofaghari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3268 7610
Email address
shafeajafar@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2022-04-19, 1401/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of plasmapheresis in comparison with conventional treatment on electrolyte and coagulation parameters in patients poisoned with aluminum phosphide

Public title
The efficacy of plasmapheresis in the treatment of patients poisoned with aluminum phosphide

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged between 20 and 65 years Poisoned with aluminum phosphide Patient/attendant consent to participate in the study

Exclusion criteria:
Any risk of coagulation disorders History of chronic kidney failure

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Considering that in this study, one group of patients will receive the usual treatment and the other group will also undergo plasmapheresis, so the specialist and the patient are aware of the type of intervention, but the person who examines the patient's condition and the data analyst will not be aware of the type of study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezar Jarib street, Azadi square.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2020-11-08, 1399/08/18

Ethics committee reference number
IR.MUI.MED.REC.1399.699

Health conditions studied

1

Description of health condition studied
Aluminum phosphide poisoning

ICD-10 code
T60

ICD-10 code description
Toxic effect of pesticides

Primary outcomes

1

Description
Systolic blood pressure

Timepoint
Immediately upon arrival at the hospital and every hour to 6 hours after the intervention

Method of measurement
Sphygmomanometer

2

Description
Diastolic blood pressure

Timepoint
Immediately upon arrival at the hospital and every hour to 6 hours after the intervention

Method of measurement
Sphygmomanometer

3

Description
Creatinine

Timepoint
Immediately upon arrival at the hospital and 12 hours after the intervention

Method of measurement
Blood test

4

Description
Sodium

Timepoint
Immediately upon arrival at the hospital and 12 hours

after the intervention
Method of measurement
Blood test

5

Description
Magnesium
Timepoint
Immediately upon arrival at the hospital and 12 hours after the intervention
Method of measurement
Blood test

6

Description
Platelets
Timepoint
Immediately upon arrival at the hospital and 12 hours after the intervention
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Patients in this group will receive only routine treatment. Continuous injection of normal saline and dopamine will be done along with olive oil gavage. In addition, intravenous administration of vitamin C at a dose of 150 mg/h, notch (NAC) at a dose of 300 mg/kg in 24 hours, 1 g magnesium sulfate and 1 g calcium gluconate every 6 hours. Vitamin E will also be given intramuscularly at a dose of 300 units every 12 hours.
Category
N/A

2

Description
Intervention group: Patients in this group will undergo plasmapheresis in addition to routine treatment. This treatment will be performed for 3 hours in the first 6 hours of the visit and the patient's plasma will be replaced with an approximate amount of 2 to 3 liters of plasmapheresis.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid hospital
Full name of responsible person
Shafeajafar Zoofaghari
Street address
Ostandari street.
City
Isfahan
Province
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81458-31451
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Email
toxicology@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjooy Javanmard
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib street, Isfahan
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Isfehan
Postal code
8174673461
Phone
+98 31 3668 8597
Email
dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person
Shafeajafar Zoofaghari

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Emergency Medicine

Street address
No. 9, Behzad alley, Sharif Vaqefi street

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shafeajafar Zoofaghari

Position
Assistant professor

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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shafeajafar Zoofaghari

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Email
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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available