Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of efficacy of erythrocyte transfusion in mortality rate of patients with aluminum phosphide contamination with coservative treatmnt: A study of randomized clinical trials

Protocol summary

Study aim
Efficacy of Erythrocyte Transfusion in Reducing Patients' Deaths with Acute Aluminum Phosphide Injury Compared to Conservative Therapy: A Randomized Clinical Trial

Design
A randomized, clinical trial study was conducted with interventional and control groups with parallel, two-way blind groups.

Settings and conduct
Baharlou Hospital is a medical, research and therapeutic center under the cover of Tehran University of Medical Sciences in southern Tehran, which has specialized in various fields including internal, surgical, pediatric, neurological, neurosurgical, eye, cardiology, etc. In this study, a number of patients who had been poisoned with Aluminum Phosphide, referred to Baharlo Hospital, and admitted to the ICU were divided into two groups of intervention and comparison: Group 1 or intervention: Patients who receive standard fresh RBC transfusion in addition to standard treatment. Group 2 or Comparison: Patients undergoing standard treatment and do not receive RBC fresh packed.

Participants/Inclusion and exclusion criteria
People over the age of 18 who have taken more than 1/4 of rice tablets and have metabolic acidosis.

Intervention groups
The intervention group receiving the fresh pack RBC and the control group that will receive only the standard treatment.

Main outcome variables
Mortality Rate for 72 Hours, Metabolic acidosis, Systolic blood pressure, Poisoning, Cardiac complications, Pulmonary complications, Liver complications, Renal complications, Responses to injectable blood, Blood transfusion complications.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180428039443N1**
Registration date: **2019-01-07, 1397/10/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-07, 1397/10/17**
Update count: **0**

Registration date
2019-01-07, 1397/10/17

Registrant information
Name
Ahmad Reza Dehpour
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-10-23, 1397/08/01
Expected recruitment end date
2020-10-22, 1399/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of efficacy of erythrocyte transfusion in mortality rate of patients with aluminum phosphide contamination with coservative treatmnt: A study of randomized clinical trials

Public title
efficacy of erythrocyte transfusion in mortality rate of patients with aluminum phosphide

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years More than 1/4 tablets of rice (aluminum phosphide) They have not been poisoned for more than 4 hours. Clinical manifestations (garlic smell, hypotension (less than 60/100 mm / Hg), gastrointestinal tract pain (retinoestromem, vomiting) Laboratory disorder including metabolic acidosis (less than 7.2)

Exclusion criteria:
People who have taken herbal pill (Banana). History of any known chronic disease (high hemoglobin, congestive failure) due to clinical diagnosis. pregnant women lactating woman History of response to blood transfusion Patients with CHF (do not have transfusion bearing erythrocyte) Patients with hemoglobin above 16

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
The random number sequences of volunteers are made by the Sealed Envelope | Randomization site. Using random quadrilateral blocks, the random chain is created at first by the number of sample volumes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Because of the nature of the outcome of the disease (death), blindness or blindness does not disclose the study. However, the final data for analysis will be coded and analyzed without the knowledge of the treatment group. Data collection authorities and those who evaluate the outcome, Data Safety and Monitoring Committee, and those who prepare the draft article, are kept blind to the studied groups.

Placebo
Not used

Assignment
Parallel

Other design features
Baharlou Hospital is a medical, research and therapeutic center under the cover of Tehran University of Medical Sciences in southern Tehran, which has dominated various specialized clinics including internal, surgical, pediatric, neurological, neurosurgical, eye, cardiology, etc. It is the special poisoning center of Tehran University Medical Sciences.In this study, a number of patients who had been poisoned with Aluminum Phosphide and referred to Baharlo Hospital and admitted to the ICU were divided into two groups of intervention and comparison: Group 1 or intervention: Patients who receive standard RBC transfusion in addition to standard transfusion.Group 2 or Comparison: Patients undergoing standard treatment and Transfusion do not receive RBC fresh packed.At first, the age, sex, marital status and occupation of patients will be recorded and will be recorded in the hospital.

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Poursina St.

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2018-11-20, 1397/08/29

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.589

Health conditions studied

1

Description of health condition studied
aluminium phosphide poisoning

ICD-10 code
T60

ICD-10 code description
Toxic effect of pesticides

Primary outcomes

1

Description
metabolic acidosis,

Timepoint
The moment of arrival, one hour after arrival, two hours

after arrival, three hours after arrival, six hours after arrival, twelve hours after arrival, twelve and four hours after arrival, forty eight hours after arrival, seventy And hours after arrival

Method of measurement

Metabolic acidosis is estimated by measuring the level of acidity in the blood.

2

Description

mortality rate

Timepoint

From the time of arrival to the moment of discharging from the hospital

Method of measurement

The mortality rate is also obtained by the number of treated patients compared to the referrals.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who receive, in addition to standard treatment, fresh packed RBC transfusion (transmitted by the blood transfusion center).

Category

Treatment - Other

2

Description

Control group: Patients undergoing standard treatment and not receiving fresh packed RBC transfusion.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharlu Hospital

Full name of responsible person

Behnam Behnoush

Street address

Baharlu Hospital, Behdari St, Tehran Province, Tehran,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran 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?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Ahmad Reza Dehpour

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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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 patient information documented data without identification. The information entered will eventually be entered in the database of the database.
When the data will become available and for how long
Data will be available upon national and international patenting process completion of the study.
To whom data/document is available
All interested researchers
Under which criteria data/document could be used
There is no specific condition.
From where data/document is obtainable
Dr. Ahmad Reza Dehpour
What processes are involved for a request to access data/document
The procedure outlined by the Ethics Committee of Tehran University of Medical Sciences.
Comments