Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of the effect of intralipid in the treatment of patients with phosphide poisoning

Protocol summary

Study aim
Comparison of therapeutic effect of interalipid with routine treatment in patients with rice pill poisoning

Design
Two arm parallel group randomised trial design of 60 patients, and outcome assessment

Settings and conduct
In this randomized clinical trial, 60 consecutive patients with Aluminum Phosphide intoxication in Baharloo Hospital in Tehran in 2020 were assessed. The cases were randomly assigned to receive either Normal saline or Intralipid (bolus dose of 1.5 ml/kg and maintenance dose of 0.25 to 0.5 ml/kg/min from 20% preparation). Systolic blood pressure, pulse rate, arterial blood pH and bicarbonate, mortality rate, and ICU stay were compared across the groups until 24 hours.

Participants/Inclusion and exclusion criteria
The study population consisted of aluminum phosphide poisoners hospitalized in Baharloo Hospital during 1397. Inclusion criteria included patients with a history of intoxication with rice pills and metabolic acid (bicarbonate less than 14) during the first 6 hours, and exclusion criteria included patient dissatisfaction and concomitant poisoning (multidrug toxicity).

Intervention groups
Both control and intervention groups were given routine treatment with aluminum phosphide poisoning. The intervention group, in addition to the usual treatment, was administered an interalipid serum as a bolus dose of 1.5ml / kg and a maintenance dose of 0.25-0.5ml / kg / min of 20% interalipid or the equivalent dose of interalipid 10%.

Main outcome variables
Heart rate, systolic blood pressure, acidosis and arterial blood pH, death

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220618055207N1**
Registration date: **2022-09-06, 1401/06/15**
Registration timing: **retrospective**

Last update: **2022-09-06, 1401/06/15**
Update count: **0**

Registration date
2022-09-06, 1401/06/15

Registrant information

Name
khadije delroba

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6659 7316

Email address
delrobakh88@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2021-03-29, 1400/01/09

Actual recruitment start date
2020-04-20, 1399/02/01

Actual recruitment end date
2021-02-18, 1399/11/30

Trial completion date
2021-09-20, 1400/06/29

Scientific title
Evaluation of the effect of intralipid in the treatment of patients with phosphide poisoning

Public title
Investigation of the effect of interalipid on aluminum phosphide poisoning
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
aluminum phosphide poisoning Metabolic acidosis (bicarbonate less than 14) during the first 6 hours
Exclusion criteria:
Dissatisfaction of patients simultaneous poisoning (multidrug toxicity)
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomized, block- Availability sampling was used and the sample size was 60 people (30 people in each of intralipid and placebo groups). At the stage of dividing into groups, as Block randomization with blocks of 5 people were divided into intralipid and placebo groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Science
Street address
Room 605 - Secretariat of the Ethics Committee in Biomedical Research of the University - Central Organization of the University, 6th Floor of the Research and Technology Vice-Chancellor - Central Organization of the University - Corner of Quds St. - Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2019-05-04, 1398/02/14
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.051

Health conditions studied

1

Description of health condition studied
Aluminium phosphide poisoning
ICD-10 code
T57.1X2
ICD-10 code description
Toxic effect of phosphorus and its compounds, intentional self-harm

Primary outcomes

1

Description
Heart rate, systolic blood pressure, acidosis and arterial blood pH, death
Timepoint
At the beginning of the study and 24 hours after the start of the intervention
Method of measurement
Vital Sign Monitor in icu

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to the usual treatment of aluminum phosphide poisoning, Serum Intralipid was administered as a bolus dose of 1.5ml/kg and maintenance dose of 0.25-0.5ml/kg/min with 20% Intralipid .
Category
Treatment - Drugs

2

Description
Control group: In addition to the usual treatment of aluminum phosphide poisoning, normal saline was administered with a bolus dose of 1.5 ml/kg and maintenance dose of 0.25-0.5 ml/kg/min.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Baharloo Hospital

Full name of responsible person
Dr. Behnam Behnoosh

Street address
Baharloo Hospital, Behdari Ave, Railway Square

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr.Akbar Fotouhi

Street address
6th floor of Research and Technology Vice-Chancellor - University Central Organization - Corner of Quds St. - Keshavarz Blvd

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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
Dr . Mohammad Arefi

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Forensic Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
demographic information and the final main outcome

When the data will become available and for how long
October after the results are published

To whom data/document is available
Researchers working in medical universities of the country

Under which criteria data/document could be used
Any use of the documentation of this Research project for analysis or carrying out other plans must be done with the knowledge and coordination and obtaining permission from the main implementers of the plan.

From where data/document is obtainable
By email to Dr. Mohammad Arefi

What processes are involved for a request to access data/document
The purpose of using the data must be completely transparent and only demographic information and the final main outcome can be sent - via email and a period of about one month.

Comments