

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 intralipid 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 intralipid serum as a bolus dose of 1.5ml / kg and a maintenance dose of 0.25-0.5ml / kg / min of 20% intralipid or the equivalent dose of intralipid 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 intralipid 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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Web page address

<https://baharloo.tums.ac.ir/>

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.
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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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Baharloo Hospital- Beehdari Street- Railway Square-
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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Dr.Mohammad Arefi

Position

Profossor

Latest degree

Subspecialist

Other areas of specialty/work

Forensic Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohammad Arefi

Position

Professor

Latest degree

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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