# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Assessment of Intravenous Levocarnitine on the mortality and morbidity of patients with aluminum phosphide intoxication

## Protocol summary

**Study aim**
Increasing the survival rate of patients with aluminum phosphide poisoning
**Design**
This study will be conducted as a randomized, controlled, open-label, parallel group assignment clinical trial, on 40 patients (20 patients in each group) in Loghman Hakim hospital.
**Settings and conduct**
Patients referred to the emergency department of Loghman Hospital with aluminum phosphide poisoning are included in the study according to the inclusion criteria and will receive standard treatment. A group of patients will also receive intravenous L-carnitine in addition to the standard treatment.
**Participants/Inclusion and exclusion criteria**
Inclusion criteria: aluminum phosphide intoxication, Positive silver nitrate test, Systolic blood pressure lower than 90 mmHg, Serum bicarbonate less than 15 mEq/L, Blood pH lower than 7.2, Cardiac output of 15 and above
Exclusion criterion: Patients or caregivers who have not provided written informed consent
**Intervention groups**
The patients are divided into two groups of control and test, both of which receive standard care (including a vasopressor, sodium bicarbonate or potassium permanganate and GIK protocol) and the test group, in addition to standard treatment, will receive 1 gram of L-carnitine intravenously every 8 hours.
**Main outcome variables**
Assessment of 24-hour mortality

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20210720051946N1**
Registration date: **2022-04-20, 1401/01/31**
Registration timing: **retrospective**

Last update: **2022-04-20, 1401/01/31**
Update count: **0**
**Registration date**
2022-04-20, 1401/01/31

**Registrant information**
**Name**
Peyman Erfan Talab Evini
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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+98 21 5102 5000
**Email address**
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2020-06-30, 1399/04/10
**Expected recruitment end date**
2022-01-20, 1400/10/30
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Assessment of Intravenous Levocarnitine on the mortality and morbidity of patients with aluminum phosphide intoxication

**Public title**
Assessment of Intravenous Levocarnitine on the mortality and morbidity of patients with aluminum

phosphide intoxication

**Purpose**

Health service research

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

aluminum phosphide intoxication Positive silver nitrate test Systolic blood pressure lower than 90 mmHg Serum bicarbonate less than 15 mEq/L Blood pH lower than 7.2 Cardiac output of 15 and above

**Exclusion criteria:**

Patients or caregivers who do not provide written informed consent

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

simple randomization, meaning: codes A and B are written on pre-prepared forms and the forms will be taken and used randomly. The patient for whom code A is assigned will receive L-carnitine and the ones with code B will not receive L-carnitine.

**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**

Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Me

**Street address**

13th Floor, Block A, Headquarters of the Ministry of Health, Treatment and Medical Education, Sima-ye-Iran street, Between South Flamek and Zarafshan St

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۹۹۴۳۴۷۱

**Approval date**

2020-06-28, 1399/04/08

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1399.273

## 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**

24-hour mortality

**Timepoint**

assessment of death within 24 hours after arrival to the hospital

**Method of measurement**

patient medical record

## Secondary outcomes

### 1

**Description**

Peripheral blood pH

**Timepoint**

every three hours

**Method of measurement**

Venous blood gas

### 2

**Description**

Peripheral Blood HCO3

**Timepoint**

every three hours

**Method of measurement**

Venous blood gas

### 3

**Description**

Blood pressure

**Timepoint**

every three hours

**Method of measurement**

sphygmomanometer

### 4

**Description**

Vasopressor administration

**Timepoint**

every three hours

**Method of measurement**
Patient medical record

## Intervention groups

### 1

**Description**
Intervention group: L-Carnitine 1 gram every 8 hours intravenously with standard care
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Standard care (a vasopressor with sodium bicarbonate or potassium permanganate and the GIK protocol (glucose, insulin, potassium)
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Loghman Hakim hospital
**Full name of responsible person**
Dr Peyman Erfantalab Evini
**Street address**
Loghman Hospital kamali st. Kargar st. Tehran. Iran
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Dr Peyman Erfantalab
**Street address**
Lashgar Intersection, Makhsous St., Loghman hakim hospital
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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**
Shahid Beheshti 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**
Alborz university of medical sciences
**Full name of responsible person**
Dr Hoorvash Farajidana
**Position**
Associate professor
**Latest degree**
Specialist
**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

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**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