

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Registration timing: **retrospective**

Study aim

Increasing the survival rate of patients with aluminum phosphide poisoning

Last update: **2022-04-20, 1401/01/31**

Update count: **0**

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.

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

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peyman1346erfan@sbmu.ac.ir

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.

Recruitment status

Recruitment complete

Funding source

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

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

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

Scientific title

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210720051946N1**

Registration date: **2022-04-20, 1401/01/31**

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

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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

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Peyman Erfan Talab Evini

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Toxicology

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Person responsible for updating data**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

Street address**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