Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

To determine the cardiovascular effects triodithyronine (T3) in patients poisoned with aluminum phosphide (AlP)

Protocol summary

Study aim
In this study, our goal is to investigate the potential of triiodothyronine (T3) in protecting and improving cardiac function in people with aluminum phosphide poisoning based on the electrocardiogram and laboratory results.

Design
This study is a randomized controlled clinical trial on acute AlP-poisoned patients

Settings and conduct
Toxicology Research Center of Mashhad University of Medical Sciences, Blood samples are taken at hospital and clinical information is recorded from the file. all diagnostic tests on samples are performed in the laboratory of the Research Center.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. A patient who has been taking rice pills for the past 3 hours. 2. sign the informed consent form. exclusion criteria: 1. The patient's silver nitrate test is negative. 2. The patient has taken non-phosphoric aluminum rice tablets (herbal type).

Intervention groups
Patients are examined and routinely treated for AlP poisoning, and the T3 will be given in the prescribed dose to trial group, while this will not done in the control group.

Main outcome variables
Examination of clinical signs and patients outcomes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130811014330N8**
Registration date: **2021-02-11, 1399/11/23**
Registration timing: **retrospective**

Last update: **2021-02-11, 1399/11/23**
Update count: **0**

Registration date
2021-02-11, 1399/11/23

Registrant information

Name
Hamid Reza Rahimi

Name of organization / entity
Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-21, 1396/12/02

Expected recruitment end date
2020-06-17, 1399/03/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
To determine the cardiovascular effects triodithyronine (T3) in patients poisoned with aluminum phosphide (AlP)

Public title
triodithyronine (T3) in aluminum phosphide (AlP) poisoning

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

aluminum phosphide (AlP) poisoning Informed consent

Exclusion criteria:

The patient's silver nitrate test is negative. The patient has taken non-phosphoric rice tablets (herbal type).

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: block Build random sequences: Randomaize.com randomization site Allocation Concealment: SNOSE (sequentially numbered, opaque, sealed envelopes) According to the two intervention and control groups, each block will be four. Then write a list of blocks and assign numbers to them, which will be 6 blocks according to the sample size of 24 people. Then random numbers between one and 6 are selected according to the Randomaize.com randomization site. Finally, the allocation list is written based on random numbers on the envelopes containing each block.

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

Ethic's committee of Mashhad University of Medical Sciences

Street address

Quraish bilding of MUMS, daneshghah St, Mashhad, Iran Mashhad

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Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2017-07-05, 1396/04/14

Ethics committee reference number

IR.MUMS.fm.REC.1396.165

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

Mortality rate

Timepoint

Since the entry of the patient in the study until death or discharge from the hospital

Method of measurement

Observation & Investigation

2

Description

Cardiovascular & hemodynamic effects

Timepoint

admission time and each 24 hours

Method of measurement

Observation & Investigation

Secondary outcomes

1

Description

Malondealdehyde

Timepoint

Beginning of the study (baseline), 12 to 24 hours after inclusion

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: Drug intervention with standard therapy. Drug intervention: Liothyronine tablet 50 mcg (a single dose) by nasogastric tube, after gastric lavage. Standard therapy: oxygen 100%; normal saline serum IV, 10-20 ml/kg; gastric lavage with sodium bicarbonate solution; dopamine IV, 5-15 mcg/kg/min; hydrocortisone IV, 100 mg qid; pantoprazole IV, 40 mg bid; magnesium sulfate IV infusion, 1gr qid; metoclopramide IV, 10 mg qid; calcium gluconate 10% qid.

Category

Treatment - Drugs

2

Description
Control group: Just standard therapy. Standard therapy: oxygen 100%; normal saline serum IV, 10-20 ml/kg; gastric lavage with sodium bicarbonate solution; dopamine IV, 5-15 mcg/kg/min; hydrocortisone IV, 100 mg qid; pantoprazole IV, 40 mg bid; magnesium sulfate IV infusion, 1gr qid; metoclopramide IV, 10 mg qid; calcium gluconate 10% qid.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza hospital

Full name of responsible person
Hamid Reza Rahimi

Street address
Imam Reza hospital Sq, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences,vice chancellor for research

Full name of responsible person
Dr Mohsen Tafaghodi

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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
Mashhad University of Medical Sciences,vice chancellor for research

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
Mashhad University of Medical Sciences

Full name of responsible person
Hamid Reza Rahimi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Genetics

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Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Clinical documentation is published with confidentiality
When the data will become available and for how long
One year after the end of sampling
To whom data/document is available
Researchers in the field of toxicology
Under which criteria data/document could be used
For further research
From where data/document is obtainable
Dr. Hamid Reza Rahimi, Dr. Seyed Reza Mousavi
What processes are involved for a request to access data/document
Approved by the Research Committee of the University Toxicology Research Center
Comments