

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Determining the effectiveness of Dihydroxyacetone (DHA) serum in the treatment of patients with aluminum phosphide (rice tablet) poisoning by assessing the blood pressure and ECG changes and cardiac function

Protocol summary

Study aim

Determining the effectiveness of dihydroxyacetone (DHA) serum in the treatment of aluminum phosphide (rice tablet) poisoning by assessing blood pressure and ECG changes and cardiac function

Design

A pre-post, phase 2 on 10 patients, uncontrolled, prospective, single-centre clinical trial.

Settings and conduct

In this study, DHA serum is intravenously infused into patients who have been poisoned with rice tablets and are admitted to Imam Hassan Hospital (North Khorasan University of Medical Sciences, Bojnurd, Iran). The study outcomes are evaluated in terms of the effectiveness of DHA before and after the infusion and until the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: People who have been poisoned with aluminum phosphide (rice tablets). Exclusion Criteria: 1- Conditions where the amount of aluminum phosphide used in rice tablets cannot be trusted; e.g., expired rice tablets, being exposed to moisture or dissolved in water before use, crushed before use, vomiting after taking the tablet. 2- Banan tablets (the same as garlic tablets) have been taken.

Intervention groups

Intravenous infusion of ready-to-inject dihydroxyacetone (DHA) serum in people poisoned with aluminum phosphide

Main outcome variables

Changes in blood pressure, changes in electrocardiogram (ECG), contractile strength of the heart by measuring EF

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150606022569N4**

Registration date: **2023-10-26, 1402/08/04**

Registration timing: **prospective**

Last update: **2023-10-26, 1402/08/04**

Update count: **0**

Registration date

2023-10-26, 1402/08/04

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3223 9001

Email address

hosseini1115@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-05, 1402/08/14

Expected recruitment end date

2025-11-05, 1404/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effectiveness of Dihydroxyacetone (DHA) serum in the treatment of patients with aluminum phosphide (rice tablet) poisoning by assessing the blood

pressure and ECG changes and cardiac function

Public title
The effectiveness of DHA serum in the treatment of aluminum phosphide poisoning

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 This study is conducted on people who have been poisoned (intentionally or unintentionally) with aluminum phosphide (rice tablets).
Exclusion criteria:
 The rice tablet(s) is/are exceeded their expiration date. The tablet(s) is/are exposed to moisture and release(s) its/their phosphine gas. The tablet(s) is/are dissolved in water prior to use and so release(s) its/their phosphine gas. The tablet(s) is/are thoroughly crushed before use, resulting in a large amount of phosphine gas being released. The tablet(s) and its/their contents are thrown out immediately after eating due to vomiting. The person ingested the "Banan tablet" (a tablet that contains garlic, salt and starch, and is sometimes erroneously referred to as the rice tablet in Iran).

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
A Prospective Pre-Post Study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

North Khorasan University of Medical Sciences

Street address

Dolat Blvd., Central Building of North Khorasan

University of Medical Sciences, Bojnurd

City

Bojnurd
Province
 North Khorasan
Postal code
 9414974877

Approval date

2022-05-22, 1401/03/01

Ethics committee reference number

IR.NKUMS.REC.1401.005

Health conditions studied

1

Description of health condition studied

Poisoning with rice tablets (aluminum phosphide)

ICD-10 code

T60.4

ICD-10 code description

Toxic effect of rodenticides

Primary outcomes

1

Description

Changes in blood pressure

Timepoint

At predetermined intervals prior to and following the administration of DHA until the death or hospital discharge.

Method of measurement

Blood pressure monitor

2

Description

Electrocardiogram (ECG) changes

Timepoint

At predetermined intervals prior to and following the administration of DHA until the death or hospital discharge.

Method of measurement

Electrocardiography

3

Description

Contractile strength of the heart by measuring EF

Timepoint

At predetermined intervals prior to and following the administration of DHA until the death or hospital discharge.

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Arterial oxygen saturation

Timepoint

At predetermined intervals prior to and following the administration of DHA until the death or hospital discharge

Method of measurement

Measurement of arterial oxygen saturation

2

Description

Blood glucose

Timepoint

At predetermined intervals prior to and following the administration of DHA until the death or hospital discharge

Method of measurement

Laboratory measurement of blood glucose

3

Description

Level of consciousness

Timepoint

At predetermined intervals prior to and following the administration of DHA until the death or hospital discharge

Method of measurement

Using the Glasgow Coma Scale (GCS)

4

Description

Mortality rate

Timepoint

End of the study

Method of measurement

Number of patients who died

5

Description

Incidence of adverse effects

Timepoint

During and following the administration of DHA until the death or hospital discharge

Method of measurement

Incidence of the adverse effect following DHA injection

6

Description

Arterial blood acidity

Timepoint

At predetermined intervals prior to and following the administration of DHA until the death or hospital discharge.

Method of measurement

Measurement of arterial blood pH

7

Description

Heart rate

Timepoint

At predetermined intervals prior to and following the administration of DHA until the death or hospital discharge.

Method of measurement

Heart rate monitor

Intervention groups

1

Description

Intervention group: The dihydroxyacetone (DHA) serum for injection, which is prepared in 500 cc bottles of 5% dextrose water at Shiraz University of Medical Sciences, is given intravenously to the patient who meets the inclusion criteria at a rate of 500 cc (one bottle) per hour. If the patient tolerates it and there are no life-threatening complications, the second and third 500 cc are administered. If needed, up to the maximum total volume of 2500 cc is infused for them.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hassan Hospital

Full name of responsible person

Leila Hosseini

Street address

Arkan road

City

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North Khorasan

Postal code

9453155174

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Email

mohammadbagher_oghazian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Bahram Bibak

Street address

Dolat Blvd., Central Building of North Khorasan University of Medical Sciences,

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nkums.research@gmail.com
Web page address
<https://research.nkums.ac.ir/index.aspx>
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bojnourd University of Medical Sciences
Proportion provided by this source
10
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

2

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hossein Niknahad
Street address
Headquarters of Shiraz University of Medical Sciences, Zand Street, opposite Palestine Street, Shiraz
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Province
Fars
Postal code
7134814366
Phone
+98 71 3242 4128
Fax
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niknahadh@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hossein Niknahad
Proportion provided by this source
90
Public or private sector
Private
Domestic or foreign origin
Domestic

Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Mohammad Bagher Oghazian
Position
Assistant Professor of Clinical Pharmacy
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Leila Hosseini
Position
Assistant Professor of Cardiology
Latest degree
Subspecialist
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Hosseini1115@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Leila Hosseini

Position

Assistant Professor of Cardiology

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

Street address

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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

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Not applicable

Title and more details about the data/document

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When the data will become available and for how long

--

To whom data/document is available

--

Under which criteria data/document could be used

--

From where data/document is obtainable

--

What processes are involved for a request to access data/document

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Comments