

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of therapeutic effect of echinacea extract on cardiovascular poisoning caused by aluminum phosphide

Protocol summary

Study aim

Evaluation of the therapeutic effect of echinacea cinerea extract on cardiovascular poisoning caused by aluminum phosphide on patients referring to Shahid Rahimi Hospital on Khorramabad

Design

This study is a phase 0 clinical trial, with a sample size of 40 patients. In this study, there are two intervention groups that are divided into two intervention and control groups according to the random allocation rule, the first group will receive routine treatment of the hospital and the second group will receive routine treatment plus Echinacea cinerea

Settings and conduct

Patients exposed to aluminum phosphide, referring in emergency room or at ICU at Shahid Rahimi Hospital on Khorramabad, will be considered for inclusion criteria and then divided into two groups and unaware of intervention. One of the groups received routine hospital treatment and the other group received routine treatment plus Echinacea cinerea, the blood sample will be acquired. Then, all patients will be screened for blood and urine tests as well as the ECG at the beginning and the length of the study. The predicted protocol for blood sampling is at the beginning of the admission, and it is repeated every 24 to 72 hours. Sample collected after centrifugation, freezing and at a temperature of 80 °C - will be maintained for further measurements. The Echinacea cinerea extracts will be administered in the form of suspension and via oral (natural or gastric tube). The duration of treatment varies from 72 hours to 1 week after admission, depending on the patient's condition. During the study, several cardiovascular factors (HR, PP, RR, PR, QRS, QTC, ST Height, T-Amplitude, hemodynamic parameters (arterial blood pressure (MAP), systolic pressure changes (SBP), cardiac output (CO), ejection fraction (EF), arrhythmia, Palpitation), as well as dyspnea, sensory changes, adult respiratory distress syndrome (ARDS), acute renal and hepatic

failure factors, and plasma factors related oxidative stress.

Participants/Inclusion and exclusion criteria

Include criteria Patients from 15 to 70 years old in both genders All acute and chronic exposures up to 6 months after the onset of poisoning Confirmation of oral intake and exposure to respiratory tract based on history and Clinical symptoms Exclude criteria Patients with underlying diseases, including diabetes, cardiovascular disease, respiratory failure, renal and hepatic impairment. Patients with receiving any medical care at other centers before entering the emergency room or hospital ICU

Intervention groups

There are two intervention groups in this study, the first one will receive the routine treatment of the hospital, and the second group will receive routine hospital treatment along with the Echinacea cinerea

Main outcome variables

Echinacea cinerea extract; Electrocardiographic changes; Systolic arterial pressure changes (SBP); mean arterial pressure (MAP); cardiac output (CO); ejection fraction (EF); ARDS; Total antioxidant capacity of plasma; Plasma pH disorder; plasma troponin I; activity level of enzymes in oxidative stress; activity of enzymes in liver damage; bilirubin; methemoglobin levels; blood glucose levels; kidney function tests; blood magnesium levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180118038426N2**

Registration date: **2018-03-19, 1396/12/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-19, 1396/12/28**

Update count: **0**

Registration date

2018-03-19, 1396/12/28

Registrant information

Name

Afshin Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3222 8901

Email address

nazary257@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect of echinacea extract on cardiovascular poisoning caused by aluminum phosphide

Public title

chinacea extract and cardiovascular poisoning caused by aluminum phosphide

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 15-70 in both genders All cases of acute and chronic exposure to 6 months after the onset of symptoms Confirmation of oral intake and respiratory exposure based on history and clinical symptoms

Exclusion criteria:

Patients with receiving any medical care at other centers, before entering the emergency room or ICU Patients with underlying illness, including: diabetes, cardiovascular disease, respiratory failure, renal and hepatic dysfunction

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with random allocation rule will be divided into two groups For this purpose, the researchers first set a total sample size and then randomly assigned a group of them to Group A and assigned the remainder to Group B. For example, in this study, with a sample size of 40, 20 balls for intervention group A and 20 ball for the intervention group B, and then the balls are randomly recorded without the replacement of the container and the resulting sequence is recorded.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study participants are unaware of the randomness and intervention

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Lorestan university of medical sciences

Street address

Moalem ave, Khorramabad town

City

Khorramabad

Province

Lorestan

Postal code

6963157444

Approval date

2017-11-20, 1396/08/29

Ethics committee reference number

ir.lums.rec.1396.324

Health conditions studied

1

Description of health condition studied

poisoning with aluminium phosphid

ICD-10 code

T 46.9

ICD-10 code description

Other and unspecified agents primarily affecting the cardiovascular system

Primary outcomes

1

Description

troponin anzyme

Timepoint

24 hours after intervention

Method of measurement

Using the Laboratory Kit

Secondary outcomes

1

Description

liver enzymes

Timepoint

at first-24-48-72 after intervention

Method of measurement

Using the Laboratory Kit

Intervention groups

1

Description

Intervention group: In the intervention group, a Echinophora cinerea extract is obtained from a dried and powdered part of the plant is given as a suspension, to patients 40mg/kg daily.

Category

Treatment - Drugs

2

Description

Control group: There is no specific intervention in the control group and no placebo is prescribed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahimi Hospital

Full name of responsible person

Afshin Nazari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Morvat Kalani

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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

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Afshin Nazari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The original outcome information will be shared

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

For use in review articles and books allowed

From where data/document is obtainable

Afshin Nazari-Khorram Abad- Kamalwand campus
-09166616669

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

after Sending an email , data will be sent within a week

Comments