

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

N-acetylcysteine as an adjuvant therapy in acute aluminum phosphide poisoning: A randomized clinical trial

Protocol summary

Study aim

To assess the safety and efficacy of N-acetyl cysteine as adjuvant therapy in patients with acute aluminum phosphide poisoning

Design

Two arm parallel group, single-blind, randomized controlled trial of 48 patients, enrolled between September 2020 and February 2021.

Settings and conduct

The trial will be conducted at "Menoufia Poison Control and Dependence Center", which is a part of "Menoufia University Hospital" located at Shebin Elkom city, Egypt. Participants and data analyzers will be blinded by making a letter for each medication used and masking the names of the medication and the intervention groups.

Participants/Inclusion and exclusion criteria

We will include patients with history of aluminum phosphide tablet ingestion and having clinical manifestations besides reliable identification of the compound (from the container or silver nitrate test) We will exclude patients less than 12-years-old, pregnant/lactating women, patients with chronic diseases, and those who dissolved the phosphide tablet in water before ingestion 5. Ingestion of air-exposed tablets 6. Patients refusal to participate

Intervention groups

Control group: Patients will receive the standard treatment [patient resuscitation, gastric decontamination, and supportive treatment (sodium bicarbonate, inotropes, intravenous fluids, electrolytes, intubation, mechanical ventilation, and anti-arrhythmic agents as indicated)]. Intervention group: Patients will receive the standard treatment. In addition, N-acetyl cysteine (produced by Rotabiogen for Pharmaceuticals Invest for Arabcomed-Egypt) will be administered as 150 mg/kg (in 200 ml 5% dextrose) by intravenous infusion over 1 hour, followed by 50 mg/kg (in 500 ml 5% dextrose) over 4 hours, then 100 mg/kg (in 500 ml 5% dextrose) over 16 hours.

Main outcome variables

All-cause mortality during hospital admission, Duration of ventilation, Duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200724048192N1**

Registration date: **2020-08-30, 1399/06/09**

Registration timing: **prospective**

Last update: **2020-08-30, 1399/06/09**

Update count: **0**

Registration date

2020-08-30, 1399/06/09

Registrant information

Name

Soha Abdel khalek

Name of organization / entity

Menoufia Faculty of Medicine Menoufia University

Country

Egypt

Phone

+20 48 2233463

Email address

soha_abdelkhalek@med.menofia.edu.eg

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-01, 1399/06/11

Expected recruitment end date

2021-02-28, 1399/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

N-acetylcysteine as an adjuvant therapy in acute aluminum phosphide poisoning: A randomized clinical trial

Public title

Antioxidants in acute aluminum phosphide poisoning

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

History of taking aluminum phosphide tablet(s) and clinical manifestations of acute aluminum phosphide poisoning
Reliable identification of the compound either by the container brought by patient attendants or subsequent confirmation with positive silver nitrate test on gastric sample in case of oral route exposure

Exclusion criteria:

Patients less than 12 years old
Pregnant and lactating women
Patients suffering from chronic diseases (e.g. diabetes mellitus, cardiovascular diseases, and hepatic or renal failure)
Tablet(s) was/were dissolved in water before ingestion
Ingestion of air-exposed aluminium phosphide tablets
Time passed since ingestion more than 8 hours
Patient who refused to participate

Age

From **12 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

We used the sealed, opaque sequentially numbered envelopes method for randomization and allocation concealment of patients included in this trial as described by Doig and Simpson (2005). We used 48 identical, opaque, letter-sized envelopes. We used 2 rolls of household aluminum cooking foil that we cut into 48 sheets (of the same width as and twice the height of the envelope). We prepared 48 envelope-sized sheets of white paper and 48 envelope-sized sheets of single sided carbon paper. We wrote "Treatment A" on 24 paper sheets and "Treatment B" on the other 24 sheets. To prepare 24 Treatment A envelopes, we selected one envelope-sized sheet of of Treatment A and placed one sheet of carbon paper on top of the Treatment A allocation paper with the carbon side facing the paper, then we put both papers inside a foil wrapper. Then, the completed insert was placed into a blank envelope with

the carbon paper closest to the front of the envelope. Finally, the envelop was sealed and we signed across the seal. We completed all the 24 Treatment A envelopes the same way. We prepared 24 Treatment B envelopes the same way as Treatment A envelopes. Both sets of envelopes were combined and we shuffled them thoroughly. Then, using a pen we marked a number on the front of each envelope sequentially from 1 to 48. The carbon paper inside the envelope transferred this number to the allocation paper inside. Finally, we placed these envelopes into a plastic container, in numerical order, ready for use. Doig GS, Simpson F. Randomization and allocation concealment: a practical guide for researchers. J Crit Care 2005;20:187-93.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants & data analyzers will be blinded. We will achieve this by making a letter for each medication used and masking the name of the medication & masking the intervention groups (data will be presented to data analyzers as groups A and B.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethical Committee of Faculty of Medicine, Menoufia University.

Street address

Yaseen Abdelghafar St

City

shebin el kom

Postal code

32511

Approval date

2019-05-26, 1398/03/05

Ethics committee reference number

19519FORE19

Health conditions studied**1****Description of health condition studied**

Acute aluminum phosphide poisoning

ICD-10 code

T60

ICD-10 code description

Toxic effect of pesticides

Primary outcomes

1

Description

All-cause mortality during hospital admission

Timepoint

At the end of the hospitalization period

Method of measurement

Clinical assessment

Secondary outcomes

1

Description

Proportion of patients requiring intubation

Timepoint

Before the intervention and one day after completion of the intervention

Method of measurement

Clinical evaluation

2

Description

Duration of ventilation

Timepoint

Before the intervention and one day after completion of the intervention

Method of measurement

Clinical evaluation

3

Description

Duration of hospitalization

Timepoint

At the end of the hospitalization period

Method of measurement

Clinical evaluation

Intervention groups

1

Description

Control group: Patients will receive the standard treatment, which is determined by the attending physician who maintains clinical responsibility for all patients. It consists of patient resuscitation, gastric decontamination, and supportive treatment (sodium bicarbonate, inotropes, intravenous fluids, electrolytes, intubation, mechanical ventilation, and anti-arrhythmic agents as indicated).

Category

Treatment - Drugs

2

Description

Intervention group: Patients will receive the standard

treatment, which is determined by the attending physician who maintains clinical responsibility for all patients. It consists of patient resuscitation, gastric decontamination, and supportive treatment (sodium bicarbonate, inotropes, intravenous fluids, electrolytes, intubation, mechanical ventilation, and anti-arrhythmic agents as indicated). In addition, N-acetyl cysteine will be administered as 150 mg/kg (in 200 ml 5% dextrose) by intravenous infusion over 1 hour, followed by 50 mg/kg (in 500 ml 5% dextrose) over 4 hours, then 100 mg/kg (in 500 ml 5% dextrose) over 16 hours. We will use this form of N-acetyl cysteine: ROTACYSSTEINE 20% (IV-INFU) 25 ml/vial, produced by Rotabiogen for Pharmaceuticals Invest for Arabcomed-Egypt. Each package contains one vial (25 ml) each 1 ml contains 200 mg of N-acetyl cysteine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Menoufia Poison Control and dependence Center at Menoufia University Hospital

Full name of responsible person

Soha Hamid Abdelkhalek

Street address

sabry abo alam

City

shebin el kom

Postal code

32511

Phone

+20 48 2052265

Email

d_sh_2007@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Menoufia Faculty of Medicine

Full name of responsible person

Dean of Menoufia Faculty of Medicine / Prof.

Mahmoud Kora

Street address

Yassin Abdel Ghaffar St, from Gamal Abdel Anasar St., Shebin El Kom

City

Shebin El Kom

Postal code

32511

Phone

+20 48 2222730

Email

medcine@menofia.edu.eg

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Menoufia Faculty of Medicine

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
Menoufia University Faculty of Medicine

Full name of responsible person
Soha Hamid

Position
consultant

Latest degree
Master

Other areas of specialty/work
Toxicology

Street address
sabry abo alam

City
shebin el kom

Province
Menoufia

Postal code
32511

Phone
+20 48 2052265

Email
d_sh_2007@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Menoufia Faculty of Medicine Menoufia University

Full name of responsible person
Soha Abdel khalek

Position
Consultant

Latest degree
Master

Other areas of specialty/work
Toxicology

Street address
El Kom St., Shibin El Koum - Menoufia - Egypt

City
shebin el kom

Province

Menoufia

Postal code

32511

Phone

+20 48 2233463

Fax

Email

soha_abdelkhalek@med.menoufia.edu.eg

Person responsible for updating data

Contact

Name of organization / entity
Menoufia Faculty of Medicine Menoufia University

Full name of responsible person
Soha Abdel khalek

Position
Consultant

Latest degree
Master

Other areas of specialty/work
Toxicology

Street address
El Kom St., Shibin El Koum - Menoufia - Egypt

City
shebin el kom

Province
Menoufia

Postal code
32511

Phone
+20 48 2233463

Fax

Email

soha_abdelkhalek@med.menoufia.edu.eg

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

We plan to share all IPD that underlie results

When the data will become available and for how long

Data will become available 12 months and ending 36 months following article publication

To whom data/document is available

Researchers from academic institutions whose proposal for the use of data has been approved by an

independent review committee identified for this purpose

Under which criteria data/document could be used

For IPD meta-analysis

From where data/document is obtainable

Data will be obtainable from the PI

What processes are involved for a request to access

data/document

A proposal for the use of data to be submitted to the PI, then evaluated by an independent review committee identified for this purpose

Comments