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

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Soha Abdel khalek
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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 envelops, 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 envelops the same way. We prepared 24 Treatment B envelops the same way as Treatment A envelops. Both sets of envelops 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: ROTACYSTEINE 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
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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
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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
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
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Soha Hamid
Position
consultant
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Master
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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
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