Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Corn oil for gastric decontamination in acute aluminum phosphide poisoning: A randomized controlled trial

Protocol summary

Study aim

To evaluate efficacy and safety of corn oil for gastric decontamination as a part of the management of patients with acute aluminum phosphide poisoning.

Design

Two arm parallel group, single blind, randomized controlled trial of 98 patients, enrolled between June 2020 and June 2021.

Settings and conduct

Tanta Poison Control Center (Emergency Hospital, Tanta University), Tanta, Egypt. Participants will be blinded by making a letter for each medication used and masking the name of the medication.

Participants/Inclusion and exclusion criteria

We will include patients (male or female, aged 12 to 70 years-old) with aluminum phosphide ingestion who present to the hospital within two hours from ingestion. We will exclude patients who vomit within one hour after ingestion, dissolve the aluminum phosphide pill(s) in water prior to ingestion, ingest or are exposed to substances other than aluminum phosphide, present more than 2 hours of having consumed aluminum phosphide, are treated for aluminum phosphide poisoning in other medical facilities before admission, and pregnant and lactating women.

Intervention groups

All patients will receive standard patient resuscitation, adequate hydration, and supportive treatment. Gastric decontamination will be carried out through aspiration of gastric contents via a nasogastric tube using 60 ml syringe, with no patient positioning or fluid instillation. In group I (control group), gastric lavage will be performed using sodium bicarbonate. In group II (intervention group), 60 ml corn oil will be administered following aspiration of gastric contents.

Main outcome variables

o All-cause mortality during hospital admission o Proportion of patients requiring intubation o Duration of ventilation o Duration of hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191030045275N2**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-02, 1399/03/13**
Update count: **0**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

Ahmad El-Ebiary

Name of organization / entity

Faculty of Medicine, Tanta University

Country

Egypt

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-01, 1399/03/12

Expected recruitment end date

2021-06-01, 1400/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Corn oil for gastric decontamination in acute aluminum phosphide poisoning: A randomized controlled trial

Public title
Corn oil for gastric wash in acute aluminum phosphide poisoning

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
ingestion of aluminum phosphide presentation to the hospital within two hours of aluminum phosphide ingestion

Exclusion criteria:
vomiting within one hour after aluminum phosphide ingestion dissolving the aluminum phosphide pill(s) in water prior to ingestion ingestion of or exposure to substances other than aluminum phosphide treatment for aluminum phosphide poisoning in other medical facilities before admission pregnancy lactation

Age
From **12 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **98**

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 98 identical, opaque, letter-sized envelopes. We used 2 rolls of household aluminum cooking foil that we cut into 98 sheets (of the same width as and twice the height of the envelope). We prepared 98 envelope-sized sheets of white paper and 98 envelope-sized sheets of single sided carbon paper. We wrote “Treatment A” on 49 paper sheets and “Treatment B” on the other 49 sheets. To prepare 49 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 49 Treatment A envelops the same way. We prepared 49 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 98. The carbon paper inside the envelope will transfer 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
Only participants will be masked. We will achieve this by making a letter for each medication used and masking the name of the medication.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tanta Faculty of Medicine

Street address
El-Giesh Street, Medical Campus of the Faculty of Medicine, Tanta University

City
Tanta

Postal code
31527

Approval date
2020-04-24, 1399/02/05

Ethics committee reference number
33797/4/20

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
At the end of the hospitalization period
Method of measurement
Clinical evaluation

2

Description
Duration of ventilation
Timepoint
At the end of the hospitalization period
Method of measurement
Clinical evaluation

3

Description
Duration of hospital stay
Timepoint
At the end of the hospitalization period
Method of measurement
Clinical evaluation

Intervention groups

1

Description
Control group (Sodium bicarbonate): 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, adequate hydration, and supportive treatment. Gastric decontamination will be carried out through aspiration of gastric contents via a nasogastric tube using 60 ml syringe.Then, gastric lavage will be performed using sodium bicarbonate.
Category
Treatment - Drugs

2

Description
Intervention group (Corn oil): 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, adequate hydration, and supportive treatment. Gastric decontamination will be carried out through aspiration of gastric contents via a nasogastric tube using 60 ml syringe. Then, 60 ml of corn oil will be administered following aspiration of gastric contents.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tanta Poison Control Center (Emergency Hospital, Tanta University)
Full name of responsible person
Professor Ahmad El-Ebiary
Street address
El-Giesh Street, Medical Campus of the Faculty of Medicine, Tanta University
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Faculty of Medicine, Tanta University
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
The investigators
Proportion provided by this source
100
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
Faculty of Medicine, Tanta University

Full name of responsible person
Dr. Fatma Elgazzar

Position
Associate professor

Latest degree
Medical doctor

Other areas of specialty/work
Forensic Medicine

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Person responsible for scientific inquiries

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Position
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Latest degree
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Other areas of specialty/work
Toxicology

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Person responsible for updating data

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Forensic Medicine

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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 6 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