

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

Phone

+20 40 3350373

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 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 49 Treatment A envelopes the same way. We prepared 49 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 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

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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

Full name of responsible person

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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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Full name of responsible person

Prof. Ahmad El-Ebiary

Position

Professor

Latest degree

Medical doctor

Other areas of specialty/work

Toxicology

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Person responsible for updating data

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Dr. Amal Saeed

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Latest degree

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Other areas of specialty/work

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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