Cola for Oesophageal Food Bolus Impaction (Cola Trial)

Published: 03-06-2019
Last updated: 15-05-2024

The objective of the study is to assess the efficacy and safety of cola as the initial treatment of complete oesophageal food bolus impactions.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON50563

Source
ToetsingOnline

Brief title
Cola Trial

Condition

- Gastrointestinal stenosis and obstruction

Synonym
food bolus in oesophagus, Oesophageal food bolus impaction

Research involving
Human

Sponsors and support

Primary sponsor: AMC Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cola, Foreign body, Oesophageal obstruction, Therapy

Outcome measures

Primary outcome

Improvement of oesophageal food bolus obstruction, defined as either complete

or partial resolution:

Complete resolution:

- Complete symptom resolution and

- The ability to swallow saliva.

Partial resolution:

- Improvement in symptoms, but not disappearance and

- The ability to swallow saliva.

Secondary outcome

Intervention complications, defined as:

- oesophageal perforation or

- mucosal laceration or

- bleeding or

- aspiration or

- any other complication requiring treatment, leading to a prolonged ED stay or

requiring hospitalization.

Study description

Background summary

Oesophageal food bolus impaction presentations are commonly seen in the emergency department (ED), with an estimated annual incidence rate of 13 per

100,000 persons.1 These patients are often acutely uncomfortable, drooling and gagging, and at risk for a variety of complications including oesophageal perforation and aspiration. Males are overly represented. Other risks include: older age, edentulousness, psychiatric disorders and alcohol intoxication.2,3 Oesophageal pathology is nearly always present,4 with strictures and eosinophilic esophagitis being the most common abnormalities.1,5 Other causes include oesophageal webs, malignancies and motility disorders.4

Current guidelines of the American and European Societies for Gastrointestinal Endoscopy (ASGE and ESGE) recommend emergent endoscopy for complete oesophageal food bolus obstructions and timely endoscopy for partial food bolus obstructions.5,3
Disadvantages of emergent endoscopic removal include: discomfort for the patient whilst waiting for the procedure; discomfort during endoscopy since adequate sedation is not given per current procedural sedation guidelines to reduce aspiration risk; risk of aspiration due to a non-fasted state; emergent health care utilisation with associated ED and gastroenterologist expenses. Both guidelines do also allow for pre-endoscopy medical management so long as it does not delay endoscopic removal3,5. A variety of non-endoscopic medications and interventions are described in the current medical literature, all with limited or conflicting studies on their use.4,6 Examples include: butyl scopolamine,7,8 glucagon,9,10 benzodiazepines,11 calcium channel blockers,12 nitrates,13,14 meat tenderizers (firmly discredited)15 and effervescent drinks like cola.

Cola as a treatment option has been promulgated for more than 20 years16. Cola has also been advocated as safe for patients in whom endoscopic removal of a food bolus is judged to be too risky.17,18 However, evidence on safety and efficacy is lacking.

We hypothesize that cola can resolve a substantial percentage of complete oesophageal obstructions.

Study objective

The objective of the study is to assess the efficacy and safety of cola as the initial treatment of complete oesophageal food bolus impactions.

Study design

multi-centre randomised clinical trial

Intervention

Canned Coca-Cola will be kept in the refrigerator of the Emergency Department.

For every new patient, a new can will be opened.
The patient will be given a bowl or will be placed by the sink because of likely regurgitation and drooling. Access to suctioning will be ensured. The patient will be asked by the treating physician or emergency medicine nurse to swallow a 25ml sip of cola from a standard medication measuring cup. The patient will always maintain an upright (sitting or standing) position. They will be asked to wait for 1 minute and if unsuccessful, to continue swallowing 25ml sips at 1-minute intervals. If still unsuccessful after 4 sips, they will *rest* for 10 minutes in an upright position and then resume 15mins after the initial sip, repeating the same protocol. If unsuccessful after the second series of 4 sips, the protocol will be discontinued. In total, the patient will drink a maximum of 200mls of cola.

Study burden and risks

In the few studies on cola use in oesophageal food bolus impaction published so far, no adverse events have been described. In studies on carbonated beverages other than cola, the incidence of adverse events varied between 0-5% and no serious adverse events were reported.
Cola treatment may induce gagging, coughing, vomiting or regurgitation. It may give discomfort.
Possible adverse events, known to occur due to food bolus impactions or endoscopic removal thereof include: oesophageal perforation, mucosal laceration, bleeding, aspiration.
We choose for Coca Cola to reduce the risk of a pneumonia in case aspiration has occurred.

Contacts

Public
AMC Amsterdam

Meibergdreef 9
Amsterdam-Zuidoost 1105AZ
NL
Scientific
AMC Amsterdam

Meibergdreef 9
Amsterdam-Zuidoost 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Presence of a complete oesophageal food bolus impaction
- Impaction of soft food (boneless)
- Age >17 years
- Signed written informed consent
- ASA class I, II or III

Exclusion criteria

- A trial of cola or another carbonated beverage before coming to hospital
- Other pre-endoscopic treatment having been given in-hospital or pre-hospital (such as nifedipine, glucagon, nitrates, butyl scopolamine, benzodiazepines, calcium channel blockers or other)
- Impaction of non-food items or food known to contain bones or fish bones
- Visible food bolus upon oral inspection
- Significant aspiration risk: reduced consciousness (GCS<14) or significant aspiration in previous medical history.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-12-2019
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	03-06-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22494
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64157.018.18
OMON	NL-OMON22494