Cola Trial

Gepubliceerd: 14-01-2020 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22494

Bron
NTR

Verkorte titel
Cola Trial

Aandoening

Oesophageal food bolus impaction

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Cola as a treatment option for complete oesophageal food bolus obstruction has been promulgated for more than 20 years. Cola has been advocated as safe for patients in whom endoscopic removal of a food bolus is judged to be too risky. However, evidence on safety and efficacy of cola as initial treatment is lacking. The current guidelines recommend an emergent endoscopy for removal of the food bolus. This treatment gives discomfort and risk of aspiration and perforation. If cola were successful in removal of the food bolus, this would greatly improve patient comfort and health care utilisation, since cola is cheap and globally available.
We hypothesize that cola can resolve a substantial percentage of complete oesophageal obstructions.

Objective: To assess the efficacy and safety of cola as the initial treatment of complete oesophageal food bolus impactions.

Study design: a multi-centre randomised clinical trial

Study population: Adult patients with symptomatic complete oesophageal food bolus impaction

Intervention: patients in the cola-arm will drink 25 millilitre sips of Coca-Cola with an interval of 1 minute and a maximum of 8 sips.

Main study parameters/endpoints: the percentage of complete or partial resolution of the oesophageal food bolus obstruction after drinking cola. We also evaluate intervention complications.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Drinking cola during complete oesophageal obstruction can be uncomfortable, however no significant complications have been reported in previous studies on cola use. Patients in the control group will be treated following current guidelines, so for them there will be no burden or extra risk

Doel van het onderzoek

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

obstructions

Onderzoeksopzet

The following will be recorded using questionnaires in Castor:

Baseline:
At baseline, the following will be recorded for all patients in both study arms:
Gender, age, nature of food bolus, impaction duration, time of presentation to the ED, remedies tried before coming to hospital, whether a GP was contacted and what advise they gave, at how many centimetres below the suprasternal notch the patient indicates the location of the bolus (if able to indicate), previous history of impactions (including number), previous endoscopic procedures and diagnoses.

During treatment:
For all patients (both study arms), the following will be recorded:
□□
When the patient has passed the food bolus:
Time of bolus passage, whether the bolus passed distally or came out orally, whether the patient thinks there is complete or partial resolution of the bolus, whether the patient aspirated, bled, still experiences pain/discomfort after passage or experiences dysp- noea. Booking of follow-up elective diagnostic endoscopy must be recorded. If this is deemed unnecessary by the gastroenterologist on call, the reason why.

□□When the patient has not passed the food bolus 30 minutes after enrolment (i.e. at the end of the study protocol):
Whether the patient aspirated, bled, still experiences pain/discomfort or feels dyspnoeic and whether the patient is still unable to pass fluids and saliva.

For the patients in the cola arm of the study only, the following will be recorded: Time of first sip of cola, how many sips in total, total amount drunk in millilitres.

In the endoscopy suite
The following information will be extracted from the endoscopy report by the site investigators: Presence, nature and location of food bolus. Manoeuvres and techniques required to dislodge the bolus. Time of bolus passage. Oral or distal passage. Complications (oesophageal perforation, mucosal laceration, bleeding, aspiration or any other complication) seen before removal and again after removal. Endoscopic diagnosis. Treatment advice, if any.

General follow up
Patients will be contacted by telephone to check for the occurrence of adverse events after discharge from the hospital after one week.

Patients who will have passed their food bolus pre-endoscopically will not need urgent endoscopy. They will however, per current guidelines, need elective diagnostic endoscopy, unless they are known to the department of gastroenterology and the gastroenterologist on call decides that endoscopy is not indicated in the patient. Results of this elective diagnostic endoscopy will be followed up through the endoscopy report.

Onderzoeksproduct en/of interventie

Treatment with cola while waiting for emergent endoscopic removal will be compared to the standard treatment according to the current ESGE guidelines: no pre-endoscopic treatment while waiting for emergent endoscopic
removal. Timing of endoscopy will be minimally affected by this study: for both study arms, endoscopic removal will be planned 30 minutes after being enrolled in the study

Intervention:
Canned Coca-Cola will be kept uncooled in an appropriate place at 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 Coca-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. Dependant of the crowding at the Emergency Department, it is not always possible to let the patient drink cola under the supervision of a nurse or physician. Therefore, in some cases the patient will be asked to keep track of time theirselves.

Contactpersonen

Publiek

Amsterdam UMC, AMC
Elise Tiebie

031655193849

Wetenschappelijk

Amsterdam UMC, AMC
Elise Tiebie

031655193849

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Presence of a complete oesophageal food bolus impaction, as manifested by
- The sensation of food stuck between the oropharynx and the epigastrium, while attempting to swallow
- The inability to swallow saliva
2. Impaction of soft food (boneless)
3. Age >17 years
4. Signed written informed consent
5. ASA I, II or III

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A trial of cola or another carbonated beverage before coming to hospital
2. 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)
3. Visible food bolus upon oral inspection
4. Non-food corpus alienum
5. Significant aspiration risk: reduced consciousness (GCS<14) or significant aspiration in previous medical history.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-12-2019

Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50563
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8312
CCMO	NL64157.018.18
OMON	NL-OMON50563

Resultaten