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A prospective randomised trial on the palatability and efficacy of Coca-Cola Zero® versus water for polyethylene glycol bowel preparation before colonoscopy

Submission date
20/07/2015

Recruitment status
No longer recruiting

Registration date
02/08/2015

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A colonoscopy is an examination of your entire large bowel using a device called a colonoscope. The colon must be clean and empty for best results. To clean the bowels, the patient is required to drink a few litres of bowel preparation solution in a short span of time. Routinely used bowel preparations such as polyethylene glycol (PEG) are safe and well tolerated, but have an unpleasant salty taste and commonly result in nausea (feeling sick). This results in some patients being unable to complete the recommended dose, leading to postponement of the colonoscopy or inadequate assessment of the colon. An unpalatable experience may also lead to patients avoiding a repeat or follow-up procedure. We aim to evaluate the use of a common soft drink beverage as a solvent for bowel preparation and give clinicians and patients a viable alternative to alleviate the problem of drinking large volumes of conventional bowel cleansing solution.

Who can participate?
Adults over 21 years old who are healthy or with mild or well controlled chronic illnesses and are scheduled for an elective colonoscopy at our institution.

What does the study involve?
Participants were randomly allocated to dissolve PEG in either drinking water or undiluted Coke Zero. Participants were encouraged to drink the preparation as quickly as could be comfortably tolerated, although a guide of at least a litre per hour was recommended. They were also advised to follow a low fibre, low residue diet on the day before the procedure and to fast from 12 midnight aside from clear fluid and the bowel preparation. All colonoscopies were performed under sedation by a single experienced endoscopist. Cleanliness of the colon was assessed by the endoscopist and two experienced endoscopy nurses. Prior to discharge each patient completed a questionnaire detailing the time taken to complete the bowel preparation, overall palatability, reactions to the preparation, willingness to drink the solution again or recommend it to others, and the worst part of the colonoscopy experience.

What are the possible benefits and risks of participating?
Benefits include knowledge gained from the study, which may allow the use of Coca Cola Zero as an alternative solvent for patients undergoing colonoscopy. Indirect benefits include results and knowledge that can be used as a basis for future studies. Risks include a potential breach of confidentiality. Also, there is a potential health hazard of drinking 2L of Coca Cola in a relatively short span of time.

Where is the study run from?
Fortis Colorectal Hospital/Fortis Surgical Hospital (Singapore).

When is the study starting and how long is it expected to run for?
From December 2013 to December 2014.

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Dr Isaac Seow-En
Prof Francis Seow-Choen

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FCHIRB/05/1213

Study information

Scientific Title
A prospective randomised trial on the palatability and efficacy of Coca-Cola Zero® versus water for polyethylene glycol bowel preparation before colonoscopy

Study objectives
To assess if Coca-Cola (Coke) Zero is a safe and effective solvent for polyethylene glycol (PEG) and is better tolerated by patients instead of water.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fortis Colorectal Hospital Institutional Review Board approval, 02/12/2013, ref: FCHIRB/05/1213

Study design
Interventional randomised controlled trial with two study branches

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Palatability, safety, and efficacy of Coca-Cola Zero as a solvent for polyethylene bowel preparation for colonoscopy

Interventions
All patients received two sachets of Fortrans (Beaufour Ipsen Pharma, Paris, France), each containing 64 g macrogol 4000, 5.7 g sodium sulphate, 1.68 g sodium bicarbonate, 1.46 g sodium chloride, 0.75 g potassium chloride and 0.1 g saccharin sodium. Patients were instructed to

dissolve each sachet of PEG in 1 L of drinking water or undiluted Coke Zero depending on the study group assigned and to complete 2 L of preparation no longer than 6 hours prior to colonoscopy.

Participants were encouraged to complete the preparation as quickly as could be comfortably tolerated, although a guide of at least a litre per hour was recommended. They were also advised to take low fibre, low residue diet the day before the procedure and to fast from 12 midnight aside from clear fluid and the bowel preparation.

All colonoscopies were performed under sedation by a single experienced endoscopist. Cleanliness of the colon was assessed by the endoscopist and two experienced endoscopy nurses who were not involved in the trial. All three were blind to the type of solvent used for the preparation. Each colon was judged to have no staining, minor staining or residual stool independently post-procedure by the three assessors and the majority consensus was later assigned by the study nurse.

Prior to discharge each patient completed a questionnaire detailing the time taken to complete the bowel preparation, overall palatability, reactions to the preparation, willingness to drink the solution again or recommend it to others, and the worst part of the colonoscopy experience. Palatability of bowel preparation was judged based on a scale of 1 to 4, with a score of 1 correlating with the best taste and 4 the worst.

Intervention Type
Other

Primary outcome measure
The palatability of the PEG+Coke solution compared to the PEG+water solution. Palatability was judged based on a four-point questionnaire which was issued to the patient prior to discharge.

Secondary outcome measures
1. Cleanliness of the bowel preparation was judged by the endoscopist as well as two endoscopy nurses during the colonoscopy
2. Adverse reactions, willingness to repeat the same solution again or recommend it to a friend were measured based on the same patient questionnaire prior to discharge after the endoscopy

Overall study start date
02/12/2013

Completion date
31/05/2014

Eligibility

Key inclusion criteria
1. Adults over 21 years old
2. Healthy or with mild or well controlled chronic illnesses. Control of systemic disease was determined on the basis of no increase in medication or development of new symptoms or complications within the past year
3. Scheduled for an elective colonoscopy at our institution

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Pregnant patients
2. Patients with suspected intestinal obstruction
3. Patients at risk of aspiration
4. Patients with serious systemic or poorly controlled chronic illnesses

Date of first enrolment
04/12/2013

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
Singapore

Study participating centre
Fortis Colorectal Hospital/Fortis Surgical Hospital
Singapore
289891

Sponsor information

Organisation
Seow-Choen Colorectal Centre Pte Ltd (Singapore)

Sponsor details
290 Orchard Road
#06-06 Paragon Shopping Centre
Singapore
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Singapore)

Results and Publications

Publication and dissemination plan
Planning to publish results of trial soon.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2016	29/01/2019	Yes	No