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Comparing soft drink vs Carbex for double contrast upper GI studies

Submission date
19/06/2014

Recruitment status
No longer recruiting

Registration date
08/07/2014

Overall study status
Completed

Last Edited
20/12/2017

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A barium swallow and meal is a type of x-ray that allows doctors to examine the upper gastrointestinal tract (GI), which includes the throat, oesophagus (foodpipe), stomach and duodenum (first part of the small intestine). It is used in diagnosing problems and diseases in these organs. Usually, x-rays will only highlight bone and other parts of the body that block radiation, which makes them easy to see. Before the barium swallow and meal test can be done, the stomach has to be extended with gas to make the pictures as clear as possible. Patients are usually given a fizzy drink called Carbex. This study compares the Carbex with the use of the fizzy soft drinks Indian tonic water and ginger ale. We believe that using soft drinks rather than Carbex will not affect the quality of the test. If the study is successful, it will help us to introduce soft drinks routinely and help to reduce costs to the NHS.

Who can participate?
Patients 18 years and older that have been referred by doctors for a barium swallow and meal to investigate their upper GI tract.

What does the study involve?
Patients are randomly assigned to take either Carbex or a soft drink. If the soft drink does not give clear enough pictures, the patient is given Carbex to drink and the test continued. There are no health implications to this and the aftercare is the same as usual. Patients are then asked to complete a short questionnaire about their experience of the test.

What are the possible benefits and risks of participating?
Patients are likely to enjoy drinking the soft drink more than the Carbex, making the examination a more pleasant experience. Drinking either fizzy drink may cause bloating which can feel uncomfortable in the stomach. This is normal for this examination and is required to produce good pictures.

Where is the study run from?
Torbay Hospital (UK).

When is the study starting and how long is it expected to run for?
The study will run from July to December 2014.

Who is funding the study?
South Devon Healthcare NHS Foundation Trust (UK).

Who is the main contact?
Dr Alexander Crowther
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14/07/030

Study information

Scientific Title
Comparing soft drink vs Carbex for double contrast upper GI studies: a randomised controlled trial

Study objectives
Can a publicly purchased soft drink (i.e. Indian tonic water/ginger ale) achieve comparable distention of the upper gastrointestinal tract in comparison to Carbex during a double contrast barium study and provide a diagnostic study?

On 31/07/2014 the anticipated start date was changed from 01/05/2014 to 18/07/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West - Cornwall & Plymouth, 16/07/2014, Ref: 14/SW/0126

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Available on request to sdhct.research@nhs.net

Health condition(s) or problem(s) studied
Oral and Gastrointestinal

Interventions
Participants are randomly allocated to one of two groups
1. Test group - drink soft drink (Indian tonic water or ginger ale) before taking barium
2. Control group - drink Carbex before taking barium
All participants then undergo upper gastrointestinal (GI) tract radiography

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Is the experimental soft drink used for gaseous distension of the upper GI tract not inferior to the gold standard Carbex against delta at study clinic?
2. Does the experimental soft drink provide a diagnostic upper GI double contrast barium study when used in the place of Carbex at study clinic?

Secondary outcome measures
1. If the soft drink effervescent agent is found to be noninferior then a superiority test will be performed to ascertain whether it is better than Carbex.

2. What are the potential cost savings of using the soft drink over Carbex within this institution and nationwide?
Both assessed at the study clinic

Overall study start date
18/07/2014

Completion date
01/12/2014

Eligibility

Key inclusion criteria
1. Any patient referred for an upper GI double contrast GI study and is able to give informed consent.
2. Include any patient over 18 not classified to belonging to a vulnerable group. No upper age limit

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Aged below 18 years of age.
2. Unable to give consent
3. Member of vulnerable group

Date of first enrolment
18/07/2014

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Radiology Department
Torquay
United Kingdom
TQ2 7AA

Sponsor information

Organisation
South Devon Healthcare NHS Foundation Trust (UK)

Sponsor details
c/o Manager of Research and Development
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Horizon Centre
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Sponsor type
Hospital/treatment centre

Website
http://www.sdhct.nhs.uk

ROR
https://ror.org/05374b979

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
South Devon Healthcare NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No