

Comparing soft drink vs Carbex for double contrast upper GI studies

| | | |
|--|---|--|
| Submission date 19/06/2014 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 08/07/2014 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 20/12/2017 | Condition category Digestive System | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
acrowther1@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Alexander Crowther

Contact details
Radiology Department
Torbay Hospital,
Lawes Bridge
Torquay
United Kingdom
TQ2 7AA
+44 (0) 1803 614567
acrowther1@nhs.net

Additional identifiers

Protocol serial number
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)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Diagnostic

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(s)

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?

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre**Radiology Department**

Torquay

United Kingdom

TQ2 7AA

Sponsor information**Organisation**

South Devon Healthcare NHS Foundation Trust (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

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 |