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A study to compare carbon dioxide and a fluid as methods of opening the colon to allow inspection and diagnosis

Submission date
07/08/2012

Recruitment status
No longer recruiting

Registration date
22/08/2012

Overall study status
Completed

Last Edited
08/06/2017

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
Diseases of the colon and rectum, such as cancer and Inflammatory bowel disease, are common causes of illness and death worldwide. Colonoscopy and CT colonography (CTC) are the most important methods of diagnosing these diseases. Colonoscopy is an examination with a long flexible instrument with a camera on the end. CTC is a special type of CT scan that looks specifically at the colon. For both colonoscopy and CTC to work best the colon must be opened up for inspection. Opening, or distending, the colon can be achieved by (gently) pumping either a gas (usually carbon dioxide) or a fluid into the colon. Usually for both colonoscopy and CTC carbon dioxide is used. However, over the last 10 years there has been a growing evidence to suggest that using body temperature water to open up the colon for inspection has several advantages, the most important of which is reduced discomfort. Its use has also been linked with quicker examination times, reduced need for sedation, and the suggestion of an increase in polyp (pre-cancerous growth) detection rates. This study is being undertaken by a research team that is designing a small robot to perform examinations of the colon. Patient comfort is very important as the better tolerated an examination the more it can be used in terms of research and health screening. As such the main aim of this study is to identify which method of opening the colon up for inspection, carbon dioxide or a fluid, is preferred in terms of comfort. The further secondary aims are to investigate which method distends the colon best in terms of exposing the inner lining of bowel for inspection, demonstrate the safe use of Klean Prep (GoLyteley in the US) as the fluid medium, and to assess how changes in patient position can affect comfort during these examinations.

Who can participate?
Participants will be medical students of both genders, aged 18-30.

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will have an MRI scan using carbon dioxide and then a further scan using a fluid. The other group will have the scans the other way around. Using a specially designed questionnaire the patients will be asked about their level of comfort during the scans. They will also have a blood test after the MRIs are done

to check that there is no change in the water and salt levels in the blood after using the fluid to open up the colon. The MRI scans will also be analysed and scored for how well the inner lining of the bowel is revealed for inspection. The results for both scan methods will then be compared. Three from each group will be chosen at random for additional scans in different positions. This will be done to assess how position change affects how well the colon is distended, and how comfort levels change with position.

What are the possible benefits and risks of participating?
Medical students will be used as they can gain additional benefits that other people cannot, making their use ethically advantageous. During the study they will be exposed to similar conditions to their future patients, helping them to develop empathy, as well as being exposed to the theory and practice of clinical trials during their undergraduate training. They will also be given a copy of their scan to encourage further learning in interpreting such scans. An additional benefit is the reassurance that can be provided by have had a scan of the colon and rectum that shows no disease. Each participant will also be compensated for their time and travel costs with a £50 reward. Young fit participants will be at minimal risk from the investigation and will be unlikely to have an undiagnosed bowel condition that may affect the results of the study. There is an extremely low risk of any complications secondary to participation in this study. However, the primary aim is to assess discomfort, so some small degree of discomfort is to be expected secondary to stretching of the colon walls. This will helped by giving medication to relax the walls, and the participants are allowed to stop at any point. There is also the potential, although this isn't expected, of a change in water or salt levels in the blood.

Where is the study run from?
St James's University Hospital, Leeds, UK.

When is the study starting and how long is it expected to run for?
The study will run between October and December 2012. Recruitment will occur over a few weeks at the beginning of October.

Who is funding the study?
European Research Council (Belgium) - CoDIR project.

Who is the main contact?
Adrian Hood
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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
v1.2

Study information

Scientific Title
A pilot study to compare carbon dioxide and a polyethylene glycol solution as methods of distending the colon for clinical investigation

Study objectives
Null hypothesis:
There is no difference between the two methods of distension in terms of patient tolerance.

Alternative hypothesis:
The polyethylene glycol solution will be better tolerated than carbon dioxide.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
There will be two groups A and B, to which the 20 participants will be randomly allocated. Group A will be MRI scanned using the chosen fluid to distend the colon. A few hours later group A will be MRI scanned using carbon dioxide. Group B will be exactly the same but using carbons dioxide first and the fluid second. As each participant will undergo both methods of distension they can compare the experiences directly, acting as their own control as it were.

Before each scan the participants will be given 20mg of Buscopan to relax the colon walls. This is standard practice when performing CT scans of the colon when using carbon dioxide and so will be given in both methods of distending the colon to avoid a source of bias. Before and after the scans using the chosen fluid, Klean Prep, a sample of venous blood will be taken for analysis.

Three participants from each group, selected at random, will undergo three further scans following their initial scan with the fluid method. This is to assess colonic distension and comfort level lying on each side and on their back.

After each scan, the subjects will be asked to rate their level of comfort using a specially designed questionnaire.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To compare patient tolerance of the use of fluid to open the colonic lumen with the use of CO2 insufflation

Secondary outcome measures
1. To assess the how well the two methods distend the colon measured by MRI scanning
2. To further demonstrate the safe use of Klean Prep as the fluid of choice for CoDIR
3. To investigate how filling the colon with fluid changes its dimensions when repositioning the patient
4. To assess patient tolerance of different positions following instillation of fluid

Overall study start date
01/10/2012

Completion date
01/01/2013

Eligibility

Key inclusion criteria

1. Aged 18-30
2. Subjects will predominantly be sourced from Leeds Medical School allowing their exposure to clinical trials during their training.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. For anatomical reasons: history of GI disease or abdominal or pelvic surgery
2. For biochemical reasons: history of chronic cardiac or renal disease
3. Contraindications for the use of buscopan: allergy to buscopan
4. History of acute angle closure glaucoma, porphyria, myasthenia gravis and unstable cardiac disease
5. Ethical considerations: non consent for trial or unable to consent for trial
6. MRI considerations: any metal, cosmetic or therapeutic, will be an absolute contraindication, claustrophobia

Date of first enrolment
01/10/2012

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Leeds Institute of Molecular Medicine
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United Kingdom
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Sponsor information

Organisation
University of Leeds (UK)

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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Research council

Funder Name
European Research Council

Alternative Name(s)
ERC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location

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