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St Mark's double balloon colonoscopy versus conventional colonoscopy study

Submission date	Recruitment status	[ ] Prospectively registered
26/10/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/02/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/05/2017	Surgery	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DBC Protocol v1.1

Study information

Scientific Title
St Mark's double balloon colonoscopy versus conventional colonoscopy: a prospective randomised controlled study designed to assess colonoscopy completion rates, patient comfort at colonoscopy and time taken to complete colonoscopy

Study objectives
1. Double balloon colonoscopy (DBC) should enable faster completion of colonoscopy procedures in patients known to have or predicted to have colons that are technically challenging to colonoscopy
2. DBC should enable more comfortable colonoscopies in patients known to have or predicted to have colons that are technically challenging to colonoscopy
3. DBC should enable a higher caecal intubation rate in patients known to have or predicted to have colons that are technically challenging to colonoscopy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Outer West London Research Ethics Committee (REC), March 2010, ref: 10/H0709/12

Study design
Prospective randomised parallel group controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Colonoscopy

Interventions
Patients are randomised to conventional colonoscopy (CC) or double balloon colonoscopy (DBC). The interventions will only involve a single 'routine' colonoscopy and there shall be no trial related follow-up of any length.

Intervention Type
Procedure/Surgery

Phase

Not Applicable

Primary outcome measure
1. To determine whether DBC when compared to CC will enable faster caecal intubation in patients known to have or predicted to have colons that are technically challenging to colonoscopy
2. To determine whether DBC when compared to CC will enable a more comfortable colonoscopy experience requiring less sedation in patients known to have or predicted to have colons that are technically challenging to colonoscopy

These outcomes will be measured during and immediately after the procedure. There will be no need for follow-up for the purposes of the trial.

Secondary outcome measures
To determine whether DBC when compared to CC will enable a higher caecal intubation rate in patients known to have or predicted to have colons that are technically challenging to colonoscopy.

These outcomes will be measured during and immediately after the procedure. There will be no need for follow-up for the purposes of the trial.

Overall study start date
01/05/2010

Completion date
01/05/2011

Eligibility

Key inclusion criteria
Patients referred St Mark's endoscopy unit for a colonoscopy who are known to have a colon that is technically challenging to colonoscopy, i.e. failed colonoscopy due to technical difficulties in the past or have had a 'difficult' colonoscopy in the past (as described in a previous colonoscopy report), or who fit one or more of the criteria that predict a technically challenging colonoscopy i.e.:
1. A low body mass index
2. A low waist-to-hip ratio
3. Female gender
4. Over 60 years of age
5. A past surgical history of hysterectomy
6. A longstanding history of constipation and/or haemorrhoids
7. A history of known sigmoid colon disease (e.g. known diverticular disease)
8. The presence of a known long, redundant colon as identified by diagnostic imaging

Participant type(s)
Patient

Age group
Senior

Sex
Female

Target number of participants
44

Key exclusion criteria
1. Patients with contraindications to conscious sedation
2. Patients with contraindications to colonoscopy
3. Patients with latex allergy (as the balloons on the DBC endoscope are made of latex)
4. Patients who are unwilling to have a colonoscopy or are unwilling to take part in the study
5. Patients lacking capacity to give informed consent

Date of first enrolment
01/05/2010

Date of final enrolment
01/05/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wolfson Unit for Endoscopy
London
United Kingdom
HA1 3UJ

Sponsor information

Organisation
North West London Hospitals NHS Trust (UK)

Sponsor details
Research and Development Department
Northwick Park Hospital
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England
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Sponsor type
Hospital/treatment centre

Website
http://www.nwlh.nhs.uk/research/gp.cfm?id=15

ROR
https://ror.org/04cntmc13

Funder(s)

Funder type
Other

Funder Name
Imotech/Fujinon (UK) - provided DBC equipment on a long-term loan at no additional cost

Funder Name
Investigator initiated and funded (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