

# St Mark's double balloon colonoscopy versus conventional colonoscopy study

<b>Submission date</b> 26/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/02/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/05/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Watford Road

Harrow

London

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