ISRCTN95152621 https://doi.org/10.1186/ISRCTN95152621

Computed tomography (CT) colonography, colonoscopy, or barium enema for diagnosis of colorectal cancer in older symptomatic patients

Submission date 07/07/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/07/2004	**Overall study status** Completed	
Last Edited 01/03/2022	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-a-new-test-to-help-diagnose-older-people-with-symptoms-of-bowel-cancer

Contact information

Type(s)
Scientific

Contact name
Dr Steve Halligan

Contact details
Department of Specialist Radiology
University College Hospital
Level 2 Podium
235 Euston Road
London
United Kingdom
NW1 2BU
+44 (0)20 7380 9010
s.halligan@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 02/02/01

Study information

Scientific Title
Computed tomography (CT) colonography, colonoscopy, or barium enema for diagnosis of colorectal cancer in older symptomatic patients

Acronym
SIGGAR1

Study objectives
CT colonography (CTC) is a new health technology for examination of the large bowel that is disseminating at a rapid rate, based on results from small trials that suggest that it is as sensitive as colonoscopy for detecting bowel cancer and large polyps but safer and more acceptable to patients. Many advocate using CTC to screen for bowel cancer (notably in the USA where the technique has received considerable media attention) but in the UK it is more likely that it will find a role for detecting bowel cancer in patients who have symptoms.

The symptoms of bowel cancer are very non-specific (e.g. abdominal pain, rectal bleeding, change in bowel habit, etc) and most people who have these symptoms won't have bowel cancer. However, they may still need to see a doctor and undergo a bowel examination in order to exclude the disease. The standard tests for looking at the large bowel are colonoscopy and barium enema. Colonoscopy involves the passage of a thin endoscope around the large bowel with a camera at its tip, looking for cancer. It is expensive, difficult to perform, and occasionally dangerous, especially in older patients. The alternative is barium enema, where the bowel is filled with liquid and x-rays then taken. A barium enema is safer, cheaper, and easier to perform than a colonoscopy but misses more cancer. CT colonography is a new test that examines the large bowel using a CT scanning machine. Intriguingly, It also affords the opportunity to look at the organs outside the large bowel, and might thus be able to determine if the patient's symptoms are coming from elsewhere. The evidence to date suggests that CTC is as sensitive as colonoscopy for detecting cancer but is also safer. It might therefore have an important role in the NHS for rapid, accurate, acceptable, safe, and cost-effective investigation of symptomatic patients.

This trial compares CTC with colonoscopy and barium enema in two parallel, prospective multicentre randomised trials (randomised 2 to 1 in favour of the standard test), with choice of the standard test depending on local factors such as availability and expertise. The detection or exclusion of significant large bowel cancer/polyps will be determined for each of the three tests, including the number and nature of any additional tests required to confidently exclude bowel cancer and the incidence, nature, and significance of incidental disease outside the large bowel detected by CTC. The frequency and nature of procedure-related adverse events will be recorded and the psychological effects of each test will be measured using validated questionnaires. Patient-specific records of costs and outcomes including the influence of having follow-up tests and multiple investigations will be obtained and models developed to compare management plans with outcome cost. We will also use the data collected to populate models that summarise the health effects and costs of these alternative diagnostic approaches in patients of differing ages, risks, and preferences.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/020201
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0016/50623/PRO-02-02-01.pdf

Added 25/02/2022:
In conjunction with the SIGGAR trial comparing methods of whole bowel examination, it became apparent that further investigation was necessary to find a reliable way of distinguishing between patients who need only flexible sigmoidoscopy (FS) examination of the lower bowel and those who require more extensive investigation of the whole bowel. A previous study of 16,000 patients with symptoms of bowel cancer found that 86% of cancers were found in the distal colon (and were therefore possible to detect at FS), but this proportion rose to 95% in patients whose symptoms did not include anaemia or an abdominal mass that the doctor could feel on examination. Therefore, it seemed likely that patients without these symptoms could be adequately investigated by FS, while any patients with anaemia or an abdominal mass would require investigation of the whole bowel.

These results were encouraging but were based on data from only one hospital, so it was important to confirm them more widely; this was the focus of the SOCCER study (long title: Is whole colon investigation by colonoscopy, CT colonography or barium enema necessary for all patients with colorectal cancer symptoms, and for which patients would flexible sigmoidoscopy suffice?). The research team was in an ideal position to do this because they already had details of the patients approached for the SIGGAR trial, which recruited from 21 NHS hospitals around the country. All of these patients eligible for the SIGGAR trial were referred to hospital with symptoms suggestive of bowel cancer. The SOCCER study collected blood test results to identify anaemia. Patients' notes and discharge letters were checked for any reference to an abdominal mass. Finally, the SOCCER study collected cancer diagnoses and deaths and confirmed whether the cancer was in the upper or lower part of the bowel.

The SOCCER study consisted of patients who took part in the SIGGAR trial as well as those who were registered as eligible for the SIGGAR trial but ultimately did not take part in that trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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

Health condition(s) or problem(s) studied
Colon cancer

Interventions
CT colonography, barium enema, colonoscopy

Intervention Type
Procedure/Surgery

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2004

Completion date
01/11/2007

Eligibility

Key inclusion criteria
Individuals with symptoms suggestive of colorectal cancer, aged 55 years or older.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
5,025

Total final enrolment
7375

Key exclusion criteria
Not provided at time of registration

Date of first enrolment

01/02/2004

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College Hospital
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
South Kensington Campus
London
United Kingdom
SW7 2AZ

Sponsor type
Government

Website
http://www3.imperial.ac.uk

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to agreements in place with data providers

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results	SIGGAR trial			No	Yes
Results article	SIGGAR trial	27/10/2007		Yes	No
Results article	SIGGAR trial	01/10/2011		Yes	No
Results article	SIGGAR trial	01/06/2012		Yes	No
Results article	SIGGAR trial	06/04/2013		Yes	No
Results article	SIGGAR trial	06/04/2013		Yes	No
Results article	SIGGAR trial	01/07/2015		Yes	No
Results article	SIGGAR trial	01/07/2015		Yes	No
Protocol (other)	SOCCER sub-study	25/02/2013	25/02/2022	No	No

Results article	Economic evaluation alongside the SIGGAR trial	26/10/2014	25/02/2022	Yes	No
Results article	SIGGAR trial	29/09/2008	25/02/2022	Yes	No
Results article	SOCCER sub-study	01/11/2017	25/02/2022	Yes	No
Results article	SOCCER sub-study	19/12/2018	25/02/2022	Yes	No
Plain English results	SOCCER sub-study	01/11/2017	01/03/2022	No	Yes