ISRCTN18040196 https://doi.org/10.1186/ISRCTN18040196

FIT for Follow-Up: a new type of stool test (faecal immunochemical test [FIT]) may offer more effective protection for people at higher risk of bowel cancer

Submission date
16/08/2010

Recruitment status
No longer recruiting

Registration date
17/08/2010

Overall study status
Completed

Last Edited
06/05/2022

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Most bowel cancers develop from adenomas, a type of small growth that grows on the bowel wall. Removing adenomas can help to prevent the development of cancer. The NHS now offers screening for bowel cancer to all men and women aged between 60 and 69 years and from 2010, the age range will be extended to 74 years. The screening test, called FOBT, looks for traces of blood in the stool. People who have a positive FOBT are offered colonoscopy, an examination in which an endoscope is used to examine the lining of the bowel for cancers and polyps. Those who have large or multiple adenomas found at colonoscopy are known to have an increased risk of developing more adenomas and possibly bowel cancer. Therefore they are currently offered surveillance colonoscopy at 3 year intervals. There are a number of problems with this approach. Colonoscopy is a costly procedure requiring a skilled doctor, and it carries a small risk of serious complications. It can miss lesions - indeed most advanced lesions (large adenomas or cancers) found at follow-up examinations were present but missed at the previous colonoscopy. Surveillance colonoscopy is also wasteful of resources because significant lesions are found in only about 3% of examinations, so 97% of surveillance colonoscopies will find either nothing or only small harmless adenomas. This is reassuring to the patient but offers no real benefit. Because more adenomas are now being found as a result of the NHS Bowel Cancer Screening Programme (BCSP), the number of surveillance colonoscopies is increasing and threatens to overwhelm available resources. A more cost-effective way of protecting people with higher-risk adenomas is required. We propose that a new type of stool test (faecal immunological test, FIT) could offer effective protection for this higher-risk group at a fraction of the cost. Only patients who had a positive FIT result would need to be offered colonoscopy. This study is designed to estimate the benefit of this approach.

Who can participate?
People who have taken part in the Bowel Cancer Screening Programme (BCSP) and have been diagnosed with large or multiple adenomas

What does the study involve?
Participants are offered the FIT at 1, 2 and 3 years. The test is very simple, requiring participants to collect a tiny amount of stool on a probe and return to the laboratory (easier than the FOBT which requires 6 stool samples). Participants who have a positive FIT result are offered a colonoscopy immediately and their next colonoscopy will be three years later. Those who do not test positive to any of the three annual FITs have their colonoscopy at 3 years in the usual way. We compare the total number of bowel lesions found in people who test positive at the 1st, 2nd or 3rd FITs with the number of lesions found at 3-year colonoscopy in those who had a negative FIT result. If most important lesions are found in the group who have positive FIT results, this would suggests that this new approach could provide effective protection and ultimately mean that colonoscopy could be used only in cases with a positive FIT result.

What are the possible benefits and risks of participating?
Participants who have a positive FIT results at Years 1 or 2 will be offered a colonoscopy early and some of them will have no adenomas detected, so it will not benefit them, but some participants will have important lesions found that would otherwise not be detected until 3 years and therefore will derive benefit. The FIT test will be offered in addition to the 3-year colonoscopy which is the current procedure and we will not be replacing their colonoscopy, so the risk of missing lesions is not increased.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
January 2011 to December 2015

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Current main contact as of 13/02/2019:
Dr Amanda Cross, amanda.cross@imperial.ac.uk
Previous main contact:
Prof Wendy S Atkin, w.atkin@imperial.ac.uk

Study website
http://www.fit4followup.org.uk/index.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 09/22/192

Study information

Scientific Title
Faecal immunochemical testing for adenoma surveillance (FIT for Follow-up study)

Acronym
FIT for Follow-Up

Study objectives
The overall objective is to test the hypothesis that annual immunochemical faecal occult blood testing (iFOBT or FIT) is a feasible, safe, acceptable and cost-saving alternative to colonoscopy surveillance for the diagnosis of advanced adenomas (AA) and early stage colorectal cancer (CRC) in patients with intermediate risk colorectal adenomas.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0922192
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0016/54340/PRO-09-22-192.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/05/2019, London – City and East REC (St Bartholomew's Hospital, North Wing, London, EC1A 7BE, UK; +44 (0)207 104 8171; cityandeast.rec@hra.nhs.uk), ref: 11/LO/0326

Study design
Pragmatic accuracy and efficiency study

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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

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

Interventions
People who have taken part in the BCSP and been diagnosed with large or multiple adenomas will be offered the FIT annually at 1, 2 and 3 years. People participating in this study who have a positive FIT will be offered a colonoscopy immediately and their next colonoscopy will be three years later. Those who do not test positive to any of the three annual FITs will have their colonoscopy at 3 years in the usual way.

Patients will receive a Patient Acceptability and Mental Well Being Questionnaire in Years 1 and 2. In Year 3, remaining patients will receive an End of Study Questionnaire that will include an additional set of questions on preferences for annual FIT vs. 3-yearly colonoscopy.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The cumulative yield of CRC/AA in those testing positive on any one of the 3 annual FITs, relative to the total CRC/AA (those testing positive on any of the FITs plus additional CRC/AA cases detected at the 3-year colonoscopy in those testing negative at all 3 FITs). From this we can calculate the proportion of cases which would go undetected if the FIT regimen was standard.

Secondary outcome measures
1. Completion and positivity rates for 1st, 2nd and 3rd annual FITs
2. Positive predictive values for detection of CRC/AA at the 1st, 2nd and 3rd FIT screenings in patients who undergo colonoscopic investigation
3. Detection rate of CRC/AA at the 3-year colonoscopy in patients who test negative at the 1st, 2nd and 3rd FIT screenings
4. Preference for annual FIT vs. 3-yearly colonoscopy for surveillance
5. Quality of life scores and subjective health status
6. Incremental costs and cost-effectiveness of the annual FIT vs. 3-yearly colonoscopy surveillance

Overall study start date
01/01/2011

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Men and women aged 60-75 years
2. Tested positive in the NHS Bowel Cancer Screening Programme (BCSP)
3. Had colonoscopy at which intermediate risk adenomas were removed during the past year
4. Were told they required a colonoscopy at 3 years
We will invite eligible participants from the entire BCSP however recruitment will be coordinated by one centre.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
8000

Total final enrolment
8009

Key exclusion criteria
Those who do not return a consent form

Date of first enrolment
01/01/2011

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
London
United Kingdom
W2 1PG

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Clinical Research Governance Office
G02, Sir Alexander Fleming Building
South Kensington campus
London
England
United Kingdom
SW7 2AZ

Sponsor type
University/education

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

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme (ref: 09/22/192)

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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	interim results in conference proceedings:	01/06/2015		No	No
Results article	results	01/06/2018		Yes	No
Results article	results	01/01/2019		Yes	No
Results article	results	01/01/2019		Yes	No
Results article	results	01/09/2019		Yes	No
Abstract results	Oral presentation for British Society of Gastroenterology 2014 Annual Meeting	09/06/2014	05/05/2022	No	No
Abstract results	abstract for British Society of Gastroenterology 2013 Annual Meeting	04/06/2013	05/05/2022	No	No
Results article	Patient attitudes towards faecal immunochemical testing	17/09/2013	05/05/2022	Yes	No
Results article	Public preferences for colorectal surveillance	13/09/2016	05/05/2022	Yes	No