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The All Adenomas study

Submission date	Recruitment status	[_] Prospectively registered
21/02/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/03/2017	Ongoing	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/08/2025	Cancer	

Plain English summary of protocol

Background and study aims

Bowel polyps are small, benign (harmless) growths found on the inner lining of the colon (end part of the large intestine) or rectum. They are not usually cancerous, however if they are found they should be removed as some will eventually turn into cancer if left untreated. People who have been found to have bowel polyps need to undergo surveillance to monitor their growth. Current UK guidelines for the surveillance of people found to have bowel polyps classify people into those who are at low, intermediate or high risk of developing bowel cancer in the future. This guideline was developed in 2002 and now needs to be re-examined. People with intermediate risk bowel polyps are currently recommended to have 3-yearly surveillance colonoscopy (test to look inside the intestine with a camera on a flexible tube). This is likely a good option for some people in the intermediate risk group, but it may not be the best option for others. The aim of this study is to evaluate the effectiveness of the current surveillance guidelines.

This study is being extended to assess surveillance in low-risk and high-risk bowel polyp groups. Under the current guidelines, people with low-risk bowel polyps are recommended either no surveillance or colonoscopy at 5 years. In contrast, people with high-risk polyps are recommended to have a colonoscopy at least every three years and maybe more frequently to begin with. The aim of this study is to assess the effectiveness of these guidelines; to understand whether it is safe for people within the low-risk group not to have a colonoscopy, and whether there are people within the high-risk group who do not require such intensive surveillance. The study also re-examines surveillance in the intermediate-risk group with longer follow-up.

Who can participate?

Men and women of any age who have bowel polyps who have had a colonoscopy

What does the study involve?

The study uses material from several high-quality databases in hospitals or from bowel cancer screening initiatives to identify groups of patients with bowel polyps. Information from routine colonoscopies conducted to the current surveillance programme is collected and used to see if patient's polyps worsen or turn into cancer at later visits.

What are the possible benefits and risks of participating?

There are no direct benefits or risks involved for those participating.

Where is the study run from?
Cancer Screening and Prevention Research Group (UK)

When is the study starting and how long is it expected to run for?
September 2006 to July 2028

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

Who is the main contact?
Prof. Amanda Cross, amanda.cross@imperial.ac.uk

Study website
http://www.csprg.org.uk/ia/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IA study: HTA 04/33/01; AA study: HTA 15/80/13

Study information

Scientific Title

The clinical effectiveness of different surveillance strategies to prevent colorectal cancer in people with low-, intermediate-, or high-risk colorectal adenomas: a retrospective cohort analysis

Study objectives
Current hypothesis:
The aim of this study is to review the long-term risk of CRC and surveillance requirements in all adenoma risk groups; assess heterogeneity in risk; identify appropriate surveillance intervals within defined risk groups; evaluate the psychological impact of surveillance, and the cost-effectiveness of alternative follow-up strategies.

Previous hypothesis:
The aim of this study is to examine the effect of surveillance on colorectal cancer (CRC) incidence; assess heterogeneity in risk; and identify the optimum frequency of surveillance, the psychological impact of surveillance, and the cost-effectiveness of alternative follow-up strategies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Hampstead, 15/03/2006, ref: 06/Q0501/45
Amendment to include All Adenomas objectives, London - Hampstead Research Ethics Committee, 10/04/2017

Study design
Retrospective observational multi-centre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Patients diagnosed with adenomas at colonoscopy, including those with low-risk adenoma(s) (one or two small adenomas), intermediate-risk adenoma(s) (three or four small adenomas, or one or two large adenomas) or high-risk adenoma(s) (five or more small adenomas, or three or more large adenomas)

Interventions
Routinely reported UK hospital data on gastrointestinal endoscopy and pathology data are collected for consecutive patients having diagnostic and surveillance procedures to identify the

study cohort (people with intermediate adenomas at a baseline visit). The same hospital dataset is used to determine the incidence of advanced adenomas or colorectal cancers at subsequent follow-up visits. The cohort is flagged to receive long-term follow-up data on bowel cancers and deaths from ONS and HSCIC.

A second dataset is created from three independent screening studies (UKFSST, English Bowel Cancer Screening Pilot and Kaiser Permanente Colon Cancer Prevention Program). The same data coding rules used in the hospital data set are used in the screening data set to determine baseline and follow-up visits, and polyp and procedural characteristics. The incidence of advanced adenomas or colorectal cancers at subsequent follow-up visits is reported.

Added 22/06/2017:
For the All Adenomas study, routinely reported UK hospital data on gastrointestinal endoscopy and pathology data are collected for consecutive patients having diagnostic and surveillance procedures to identify the study cohort (people with adenomas at a baseline visit). Data on long-term CRC incidence and mortality, as well as CRC staging and pathology, are determined from NHS Digital, Office for National Statistics (ONS), NHS National Services Scotland (NHS NSS) and the Public Health England Office for Data Release (PHE-ODR).

Intervention Type
Other

Primary outcome measure
Current primary outcome measures as of 22/06/2017:
Incidence of adenomas, advanced adenomas and colorectal cancer (CRC) at follow-up visits will be measured through medical record review. Long-term CRC incidence will be determined from ONS / NHS Digital / NHS NSS and PHE-ODR data.

Previous primary outcome measures:
Incidence of adenomas, advanced adenomas and colorectal cancer (CRC) at follow-up visits will be measured through medical record review and long-term CRC incidence will be determined from ONS/HSCIC data.

Secondary outcome measures
1. Psychological impact (anxiety, bowel cancer worry, number of GP visits and bowel symptoms) was measured using a questionnaire sent to participants who took part in the UKFSST screening study 6-months before screening and 3-6 months after screening
2. The health-economic analysis will take the form of an incremental cost-effective analysis of intermediate risk patients in the hospital data set, using a state-transition model. Two key health economic outcomes will be reported – cost per cancer avoided and cost per life year saved.

Overall study start date
01/09/2006

Completion date
01/07/2028

Eligibility

Key inclusion criteria

Current inclusion criteria as of 22/06/2017:
1. Men and women
2. Any age
3. With low-, intermediate- or high-risk adenomas who have undergone a baseline colonoscopy

Previous inclusion criteria:
1. Men and women
2. Any age
3. With intermediate adenomas who have undergone a baseline colonoscopy

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
65,000 people with low-, intermediate or high-risk adenomas

Total final enrolment
33011

Key exclusion criteria
1. Any of the following diagnoses at, or prior to, baseline:
1.1. CRC or inflammatory bowel disease (IBD)
1.2. Resection/anastomosis
1.3. Volvulus
2. Any of the following diagnoses at any time:
2.1. Family history of familial adenomatous polyposis (FAP)
2.2. HNPCC
2.3. Cowden syndrome
2.4. Juvenile or hamartomatous polyps
3. Patients with polyposis could be excluded depending on polyposis type and time of diagnosis
4. No baseline colonoscopy
5. One or more procedures without a date
6. More than 40 endoscopic procedures recorded

Date of first enrolment
01/08/2007

Date of final enrolment
31/07/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cancer Screening and Prevention Research Group
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Sponsor type
University/education

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

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The Intermediate Adenoma study results were published in Lancet Oncology in April 2017 (e-Pub). The corresponding NIHR Final Report was published in the Health Technology Assessment journal in June 2017. The NIHR Final Report of the All Adenomas Study will also be published by the NIHR Journals Library and the plan is to publish the study results in a high-impact journal in 2018.

Intention to publish date
01/07/2029

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2017		Yes	No
Results article	results	01/06/2017		Yes	No
Abstract results	Abstracts of the BSG Campus 2021	21/01/2021	05/05/2022	No	No
Other publications	colorectal cancer incidence in 3-yearly surveillance post-polypectomy	19/08/2020	05/05/2022	Yes	No
Results article	Long-term colorectal cancer incidence results	17/01/2020	05/05/2022	Yes	No
Results article	Principles for Evaluation of Surveillance After Removal of Colorectal Polyps	30/03/2020	05/05/2022	Yes	No
Results article	adenoma characteristics associated with proximal colon cancer	11/02/2022	05/05/2022	Yes	No
Results article	evaluation of the 2020 UK post-polypectomy surveillance guidelines	05/03/2021	05/05/2022	Yes	No
Results article	optimal surveillance intervals for advanced neoplasia detection rates	11/04/2022	05/05/2022	Yes	No
Results article	post-polypectomy and post-colorectal cancer resection surveillance guidelines	27/11/2019	05/05/2022	Yes	No
Results article	publication on the necessity of surveillance colonoscopy for patients with bowel polyps	15/05/2020	05/05/2022	Yes	No
Funder report results	results and plain language summary in Health Technology Assessment	01/05/2022	08/06/2022	Yes	No
Results article		07/08/2025	12/08/2025	Yes	No