

# The All Adenomas study

|  |   |   |
|--|---|---|
| <b>Submission date</b><br>21/02/2017   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>15/03/2017 | <b>Overall study status</b><br>Ongoing            | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>12/08/2025       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## 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

## Contact information

**Type(s)**  
Public

**Contact name**  
Prof Amanda Cross

**ORCID ID**  
<https://orcid.org/0000-0002-0893-2377>

**Contact details**  
Room 1089  
Department of Surgery and Cancer  
Imperial College London  
Queen Elizabeth The Queen Mother (QEQM) Building  
St Mary's Hospital  
London  
United Kingdom  
W2 1NY

## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Screening

### **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(s)**

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.

## **Key secondary outcome(s)**

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.

## **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

### **Healthy volunteers allowed**

No

### **Age group**

All

**Sex**

All

**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**

United Kingdom

England

**Study participating centre****Cancer Screening and Prevention Research Group**

Room 1089

Department of Surgery and Cancer

Imperial College London

Queen Elizabeth The Queen Mother (QEQM) Building

St Mary's Hospital

London

United Kingdom

W2 1NY

**Sponsor information**

**Organisation**

Imperial College London

**ROR**

<https://ror.org/041kmwe10>

**Funder(s)****Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), 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, Cancer Research UK (CRUK), CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

**Results and Publications**

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