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Study of colonoscopic surveillance intervals after removal of colorectal adenomas

Submission date	Recruitment status	[_] Prospectively registered
07/06/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/06/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/03/2017	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 colposcopies in order to monitor the growth of polyps and check for new ones. This involves having a thin, flexible tube with a camera on the end being inserted into the anus to look at the lining of the large intestine. The aim of this study is to find out how often these colonoscopies should take place to best monitor patients with bowel polyps to prevent the development of cancer.

Who can participate?
Patients aged between 20 and 71 attending St Mark's Hospital between 1979-1990 with bowel polyps or bowel cancer.

What does the study involve?
Patients are divided into groups depending on their risk of developing bowel cancer. Those who have a high risk are randomly allocated to undergo colonoscopies at 12-18 month intervals or every three years. Those who have a low risk are randomly allocated to undergo examinations every three years or every five years. Throughout the study, all patients are monitored for the development of bowel cancer and at the end of the study, the best possible frequency of monitoring is determined.

What are the possible benefits and risks of participating?
Not provided at time of registration

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 1979 to January 1990

Who is funding the study?
1. National Institute for Health Research, Health Technology Assessment Programme (UK)
2. Cancer Research UK (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 04/33/01

Study information

Scientific Title
Randomised trial of colonoscopic surveillance intervals after removal of colorectal adenomas

Study objectives
The study was designed to compare the effectiveness of different frequencies of colonoscopic examination, with polypectomy of all adenomas detected, for preventing advanced adenomas and colorectal cancer (CRC).

A secondary aim of this study was to identify baseline risk factors for diagnosis of advanced neoplasia (adenomas and CRC) during follow-up. This approach was adopted to determine if a subgroup of patients might benefit from more intense surveillance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not applicable because ethical approval standards were not in place when the study was started in the late 1970s early 1980s.

Study design
Single-centre stratified randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

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

Interventions
Study of colonoscopic surveillance regimens. Allocation to regimen was by minimisation method. Patients were stratified into high and low risk groups by their characteristics at entry (age, malignancy and multiplicity of adenomas). Then within the high risk group the participants could be randomised to frequent follow-up or exams at three year intervals. Within the low risk group paricipants could be randomised to exams at three year intervals or exams at five year intervals. No masking, all participants received surveillance.

High risk patients:
Three exams at 12-18 month intervals and 3-yearly follow-up thereafter (median endoscopic surveillance - 7.0 yrs, median passive follow-up - 18.6 yrs) or exams at three year intervals (median endoscopic surveillance - 6.6 yrs, median passive follow-up - 18.8 yrs)

Low risk patients:
Exams at three year intervals (median endoscopic surveillance - 9.1 yrs, median passive follow-up - 21.7 yrs) or exams at five year intervals (median endoscopic surveillance - 6.3 yrs, median passive follow-up - 21.8 yrs)

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
The primary outcome was the diagnosis of advanced neoplasia (advanced adenomas or colorectal cancer) during follow-up. An advanced adenoma was defined as an adenoma ≥ 10 mm or with high grade dysplasia.

Secondary outcome measures
Detection of any adenoma during follow-up.

Overall study start date
01/01/1979

Completion date
01/01/1990

Eligibility

Key inclusion criteria
1. Patients attending St Marks Hospital between 1979-1990, with endoscopically removed adenomas or malignant lesions
2. 468 males and 317 females in the study, aged between 20 and 71

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
785 patients were recruited

Key exclusion criteria
1. History of inflammatory bowel disease
2. Surgical resection for CRC
3. A rectal villous adenoma
4. Patients older than 70 years

Date of first enrolment
01/01/1979

Date of final enrolment
01/01/1990

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Imperial College London
Kensington
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W2 1PG

Sponsor information

Organisation
Imperial College London

Sponsor details
Clinical Research Governance Office
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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
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/03/1992		Yes	No