

# Cost-effectiveness of intensive versus no scheduled follow-up in patients who have undergone resection for colorectal cancer with curative intent - main trial

<b>Submission date</b> 18/05/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/05/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/10/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-followup-after-colorectal-surgery>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

ClinicalTrials.gov (NCT)

NCT00560365

**Protocol serial number**

HTA 99/10/99

## Study information

**Scientific Title**

A randomised controlled trial to assess the cost-effectiveness of intensive versus no scheduled follow-up in patients who have undergone resection for colorectal cancer with curative intent - main trial

**Acronym**

FACS (Follow-up After Colorectal Surgery)

**Study objectives**

Colorectal cancer is a major health problem. In the UK, each year about 32,000 cases are diagnosed annually and 17,000 deaths are attributed to the disease. Surgery is the mainstay of treatment and traditionally patients who have curative surgery for colorectal cancer are subject to long-term follow up. Various protocols are used by surgeons but few, if any, are evidence based. The costs to the NHS of follow-up are substantial and they need to be justified by evidence of cost-effectiveness.

Whilst a number of previous studies have assessed the value of follow up of patients with curatively resected colorectal cancer, none provides a definitive answer. This trial aims to do so. FACS is a Multicentre, randomised, controlled, intention to treat with a 2x2 factorial design. Patients randomised to 1 of 4 arms.

Details of the study can also be found at: <http://www.hta.ac.uk/1389>

FACS pilot on <http://www.controlled-trials.com/ISRCTN61091474>

Please note that extensive amendments have been made to this trial records as of 09/02/2009. They include the following:

1. The anticipated end date of this trial has been updated from 31/03/2011 to 31/08/2009.
2. The target number of participants has been amended from 4,760 to 1,000.

Other changes are recorded in the relevant fields.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

South West Research Ethics Committee (formerly SWMREC), approved on 04/02/2002 (ref: MREC /01/6/91)

**Study design**

Multi-centre randomised controlled trial, intention to treat with a 2 x 2 factorial design

**Primary study design**

Interventional

**Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Colorectal cancer

## **Interventions**

Monitoring of carcinoembryonic antigen (CEA) in primary care vs intensive imaging in hospital.

Patients randomised to 1 of 4 arms:

Arm 1: Symptomatic follow-up in primary care

Arm 2: CEA in primary care, 3 monthly for 2 years and 6 monthly for another 3 years.

Arm 3: Hospital based imaging with CT 6 monthly for 2 years and annually for another 3 years.

Arm 4: Combination of 2 and 3

All groups: Given patient handbook detailing symptoms suggestive of recurrence, colonoscopy at trial end (5 years). Contact with Colorectal Nurse Specialist can continue.

Groups 3 and 4: Additional colonoscopy at year 2.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Current primary outcome measure amended as of 11/02/2009:

Number of recurrences in each group treated surgically with curative intent, analysed at study end (5 years).

Previous primary outcome measure:

Overall survival by intention to treat analysis.

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

Current secondary outcome measures as of 11/02/2009:

1. Overall survival by intention to treat analysis, reviewed at study end (5 years)
2. Quality of life in survivors, assessed at baseline, and then at the end of study years 1-5 by the following:
  2. 1. Euroqol EQ-5D
  2. 2. European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30)
  2. 3. Hospital Anxiety and Depression (HAD) scale
  2. 4. Modified form of a College of Health Questionnaire
  2. 5. A small number of items from the 7-item questionnaire used by Kjeldsen
3. Cost of NHS services utilised, data are collected at the end of study years 1-5 for all patients
4. NHS cost per life-year saved, assessed at study end (5 years)

Previous secondary outcome measures:

1. Quality of life in survivors
2. Cost of NHS services utilised
3. NHS cost per life-years saved

## **Completion date**

31/08/2009

## Eligibility

### Key inclusion criteria

Patients who have undergone resection for colorectal cancer with curative intent

Added as of 23/01/2009:

Both males and females, 50 years and older

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Senior

### Sex

All

### Total final enrolment

1202

### Key exclusion criteria

Does not meet inclusion criteria

### Date of first enrolment

01/04/2004

### Date of final enrolment

31/08/2009

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

Professor of Surgery

Southampton

United Kingdom

SO16 6YD

# Sponsor information

## Organisation

University of Southampton (UK)

## ROR

<https://ror.org/01ryk1543>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

# Results and Publications

## 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?
<a href="#">Results article</a>	results	15/01/2014		Yes	No
<a href="#">Results article</a>	results	01/01/2021	11/01/2021	Yes	No
<a href="#">Plain English results</a>		12/01/2016	29/10/2021	No	Yes