

# 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 - pilot study

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/05/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

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

## Study website

<http://www.facs.soton.ac.uk/>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 99/10/09

## Study information

Scientific Title

Acronym

FACS (Follow-up After Colorectal Surgery)

### Study objectives

Aim: To assess the cost-effectiveness of intensive versus no scheduled follow-up in patients who have undergone resection for colorectal cancer with curative intent.

Objectives:

1. To confirm the feasibility of recruiting 5000 participants from 20 centres to the trial in two years.
2. To assess the effectiveness and cost-effectiveness of serial blood CEA measurement in detecting treatable recurrence and thereby improving 5 year survival.
3. To assess the effectiveness and cost-effectiveness of hospital follow-up involving regular ultrasound and CT imaging compared with no imaging and follow-up in general practice in detecting treatable recurrence and thereby improving 5 year survival.

Details of this study can also be found at: <http://www.hta.ac.uk/1229>

The ISRCTN record of main FACS trial that followed this pilot study can be found at: <http://www.controlled-trials.com/ISRCTN41458548>.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration.

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

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

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

Cancer (neoplasms): Rectum; Cancer (neoplasms): Colon

**Interventions**

Monitoring of carcinoembryonic antigen (CEA) in primary care vs intensive imaging in hospital. Follow-up after 3 months.

See details of ISRCTN41458548: FACS main trial on <http://www.controlled-trials.com/isrctn/trial/ISRCTN41458548/0/41458548.html>

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Not provided at time of registration.

**Secondary outcome measures**

Not provided at time of registration.

**Overall study start date**

01/09/2002

**Completion date**

29/02/2004

**Eligibility****Key inclusion criteria**

Patients who have undergone resection for colorectal cancer with curative intent.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Both

**Target number of participants**

Not provided at time of registration.

**Key exclusion criteria**

Not provided at time of registration.

**Date of first enrolment**

01/09/2002

**Date of final enrolment**

29/02/2004

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**School of Medicine**

Southampton

United Kingdom

SO16 6YD

## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

Quarry House

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**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/en/index.htm>

**ROR**

<https://ror.org/03sbpja79>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

## **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