

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

Submission date 25/04/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/04/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/05/2012	Condition category 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

Prof John Primrose

Contact details

School of Medicine
University of Southampton
Biomedical Sciences Building
Bassett Crescent East
Southampton
United Kingdom
SO16 6YD
+44 2380 796144
j.n.primrose@soton.ac.uk

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

Quarry Hill

Leeds

United Kingdom

LS2 7UE

+44 (0)1132 545 843

Sheila.Greener@doh.gsi.gov.uk

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