ISRCTN41458548 https://doi.org/10.1186/ISRCTN41458548

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

Submission date
18/05/2004

Recruitment status
No longer recruiting

Registration date
18/05/2004

Overall study status
Completed

Last Edited
29/10/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Prof John Primrose

Contact details
Professor of Surgery
F Level, Centre Block
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 (0)23 80 796144
j.n.primrose@soton.ac.uk

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)

Primary study design
Interventional

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

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?
Results article	results	15/01/2014		Yes	No
Results article	results	01/01/2021	11/01/2021	Yes	No
Plain English results		12/01/2016	29/10/2021	No	Yes