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What carcinoembryonic antigen (CEA) level should trigger further investigation during colorectal cancer follow-up?

Submission date 27/03/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/04/2013	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 16/06/2017	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00560365

Secondary identifying numbers
HTA 99/10/99 and HTA 11/136/81

Study information

Scientific Title
What carcinoembryonic antigen (CEA) level should trigger further investigation during colorectal cancer follow-up? - an observational diagnostic data analysis

Acronym
FACS add-on study 2

Study objectives
It is feasible to increase the sensitivity of blood CEA as an indicator of recurrent colorectal cancer while retaining an acceptable level of specificity by specifying a positive result in terms of the change in blood CEA level over time rather than the absolute level of a single measurement.

Pilot study on http://www.isrctn.com/ISRCTN61091474
Main trial on http://www.isrctn.com/ISRCTN41458548

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS South-West Reserach Ethics Committee, 04/02/2002, ref: MREC/01/6/91

Study design
Observational diagnostic analysis of data collected for an ongoing randomised controlled trial

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Not specified

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Colorectal cancer follow-up

Interventions
3-6 monthly blood CEA testing (already completed)

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
The main outcomes (cancer recurrence, treatment of recurrence with curative intent, and death) are monitored continuously. Blood CEA levels are measured 3 monthly for 2 years and 6 monthly for the next 3 years.

Secondary outcome measures
This add-on analysis examining the diagnostic value of different methods of interpreting blood CEA to detect recurrence will include all outcomes at two time points - 3 years (interim analysis) and 5 years (final analysis) after trial entry.

Overall study start date
01/04/2013

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. Diagnosis of primary colorectal cancer. Stage I-III disease
2. Have undergone curative resection (i.e., no residual disease [R0]). Microscopically clear margins
3. Complete normal colonic imaging pre-operatively (or post-operatively if unable to view complete colon pre-operatively) by colonoscopy, barium enema, CT pneumocolon, or virtual colonoscopy
4. Post-operative blood CEA ≤ 10 ng/mL (if the normal range is ≤ 5 ng/mL) OR < 2 times upper limit of normal (if normal range is > 5 ng/mL). For patients undergoing adjuvant therapy, CEA should be measured after completion of chemotherapy
5. Has completed primary curative treatment, as deemed by hospital clinician. Patients awaiting stoma closure allowed
6. No evidence of metastatic disease on pre- or post-operative liver CT scan (or ultrasound) and chest CT scan (or chest x-ray)
7. No diagnosis of familial adenomatous polyposis (FAP) or dominantly inherited colon cancer
8. No concurrent serious illness
9. History of other carcinoma allowed provided primary treatment has been completed, there is no evidence of recurrent disease, and there is no follow-up that conflicts with study follow-up
10. Pre-operative radiotherapy or chemoradiotherapy for rectal cancer allowed provided curative resection has been achieved
11. No concurrent participation in a primary treatment clinical trial with conflicting follow-up requirements
12. Participation in the FACS trial in one of the two arms being followed-up with regular scheduled blood CEA tests.

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
The 600 participants have already beeen recruited and 6000 blood test results are available for analysis analysis

Key exclusion criteria
1. Did not meet inclusion criteria
2. Unable to give written informed consent

Date of first enrolment
01/04/2013

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Department of Primary Care Health Sciences
Oxford
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Sponsor information

Organisation
Oxford University (UK)

Sponsor details
Radcliffe Observatory Quarter
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Sponsor type

University/education

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

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	01/04/2017		Yes	No