

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

Submission date 27/03/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/04/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/06/2017	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

ClinicalTrials.gov (NCT)
NCT00560365

Protocol serial number
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

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Oxford University Department of Primary Care Health Sciences

Oxford

United Kingdom

OX2 6GG

Sponsor information

Organisation

Oxford University (UK)

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2017		Yes	No