

A multicentre trial to evaluate the use of serial carcinoembryonic antigen (CEA) assay as the prime indicator for second-look surgery in recurrent colorectal cancer

Submission date 01/07/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/05/2014	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

Contact name

Dr - -

Contact details

UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

Protocol serial number

CRCGICEA

Study information

Scientific Title

Study objectives

Not provided at time of registration

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

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

Colon, rectum

Interventions

All patients receive primary potentially curative surgery. Patients are randomised if a significant rise in serum CEA is detected to either:

1. Conventional Arm: Observation only. The patient is monitored until there is clinical evidence of recurrent disease. The clinician is not informed of the rise in serum CEA.
2. Aggressive Arm : The surgeon is informed of the rise in serum CEA, and in the absence of objective evidence either of a non-malignant cause for the CEA rise or of incurable distant metastases, second-look laparotomy is carried out to locate and remove treatable recurrence.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2000

Eligibility

Key inclusion criteria

1. Aged 75 or under
2. Potentially curative resection performed for colorectal adenocarcinoma
3. No evidence of distant incurable spread (clinically or at surgery)
4. No evidence of hepatic, renal, pancreatic or infective disease
5. Willing to attend regular CEA monitoring in addition to clinical follow-up for 5 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex**Key exclusion criteria**

Not provided at time of registration

Date of first enrolment

01/01/1998

Date of final enrolment

31/12/2000

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information**Organisation**

Cancer Research UK (CRUK) (UK)

ROR

<https://ror.org/054225q67>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

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	13/05/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes