

# 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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### 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

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 measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/1998

**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

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**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**

England

United Kingdom

**Study participating centre**  
**UKCCCR Register Co-ordinator**  
London  
United Kingdom  
NW1 2DA

## **Sponsor information**

**Organisation**  
Cancer Research UK (CRUK) (UK)

**Sponsor details**  
PO Box 123  
Lincoln's Inn Fields  
London  
United Kingdom  
WC2A 3PX  
+44 (0)207 317 5186  
kate.law@cancer.org.uk

**Sponsor type**  
Charity

**Website**  
<http://www.cancer.org.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, CRUK

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Other non-profit organizations

### **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?
<a href="#">Results article</a>	results	13/05/2014		Yes	No