ISRCTN76694943 https://doi.org/10.1186/ISRCTN76694943

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 16/05/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
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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?
Results article	results	13/05/2014		Yes	No