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ISAAC: a randomised trial for patients with asymptomatic advanced colorectal cancer to look at the benefits of undergoing surgical removal of their primary tumour before receiving chemotherapy for metastatic disease

Submission date 31/10/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/11/2008	**Overall study status** Completed	
Last Edited 19/03/2020	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-surgery-chemotherapy-advanced-bowel-cancer-isaac

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2008-005911-16

IRAS number

ClinicalTrials.gov number
NCT01086618

Secondary identifying numbers
UCL08/0079

Study information

Scientific Title
ISAAC: a randomised trial of Initial Surgery in Advanced Asymptomatic Colorectal cancer patients receiving chemotherapy for metastatic disease

Acronym
ISAAC

Study objectives
The ISAAC trial aims to investigate whether survival is improved by resection of the asymptomatic primary tumour prior to chemotherapy compared to chemotherapy alone in patients with advanced colorectal cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Research Ethics Committee, 15/07/2009, ref: 09/H1102/60

Study design
Multicentre phase II randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Colorectal cancer

Interventions

1. Resection of the asymptomatic primary tumour prior to chemotherapy
2. Chemotherapy alone

There is no prescribed treatment in this trial. The chemotherapy regimen is at the discretion of each treating clinician who may choose the standard treatment for that hospital or the patient can be entered into a chemotherapy treatment trial. The surgical treatment is at the discretion of the treating surgeon.

Intervention Type
Mixed

Primary outcome measure
Overall survival
Patients will be followed up every 3 months until death for survival and adverse events related to surgery or chemotherapy.

Secondary outcome measures
1. Morbidity of chemotherapy and surgery
2. Quality of life, assessed at 3 months and 6 months only
3. Economic evaluation
Patients will be followed up every 3 months until death for survival and adverse events related to surgery or chemotherapy.

Overall study start date
01/06/2009

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Histologically or cytologically proven colorectal cancer
2. Metastases which are unresectable at presentation in the opinion of the appropriate multi-disciplinary team (MDT)
3. Primary tumour that in the MDT's opinion does not require immediate or emergency surgery or intervention
4. Patients who are referred for prophylactic colonic stents are eligible
5. Patient considered fit for systemic chemotherapy and surgery as determined by the local colorectal cancer MDT
6. Adequate full blood count (haemoglobin [Hb] greater than 10.0 g/dl; white blood cell count [WBC] greater than 3.0 x 10^9/L; platelets [Plts] greater than 100 x 10^9/L)
7. Adequate renal biochemistry: calculated glomerular filtration rate (GFR) greater than 50 ml /min using the Wright formula or measured by ethylenediaminetetraacetic acid (EDTA) clearance
8. Adequate hepatobiliary function: bilirubin less than 25 mmol/l
9. World Health Organization (WHO) performance status of 0 or 1
10. If female and of childbearing potential, must have a negative pregnancy test prior to trial entry and agree to avoid pregnancy during the trial
11. Patients over 18 years of age (either sex) able and willing to provide written informed consent for the trial and able to comply with treatment and follow-up schedule

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Serious co-morbidity precluding systemic chemotherapy
2. Unresectable primary tumour
3. Unequivocal extensive peritoneal metastases
4. History of malignant disease in the preceding five years with the exception of non-melanomatous skin cancer and in situ cervical cancer
5. Serious medical co-morbidity, e.g. uncontrolled inflammatory bowel disease, uncontrolled angina or recent (less than six months) myocardial infarction, another serious medical condition judged to compromise ability to tolerate chemotherapy and/or surgery
6. Less than 18 years of age
7. Pregnant or breast feeding

Date of first enrolment
01/06/2009

Date of final enrolment
29/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospital
London
United Kingdom
W1P 8BT

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

Website
http://www.ctc.ucl.ac.uk

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C32436/A10431)

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