

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/11/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/03/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-surgery-chemotherapy-advanced-bowel-cancer-isaac>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2008-005911-16

ClinicalTrials.gov (NCT)

NCT01086618

Protocol serial number

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

Study type(s)

Treatment

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(s)

Overall survival

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

Key secondary outcome(s)

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.

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 $3.0 \times 10^9/L$; platelets [Plts] greater than $100 \times 10^9/L$)
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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

University College London Hospital

London

United Kingdom

W1P 8BT

Sponsor information

Organisation

University College London (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, 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