

SCOT - Short Course Oncology Therapy: a study of adjuvant chemotherapy in colorectal cancer

Submission date 10/07/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/08/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/06/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-to-find-out-how-long-to-give-chemotherapy-after-surgery-for-bowel-cancer>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2007-003957-10

IRAS number

ClinicalTrials.gov number

NCT00749450

Secondary identifying numbers

SCOT 2007-01

Study information

Scientific Title

SCOT - Short Course Oncology Therapy: a study of adjuvant chemotherapy in colorectal cancer by the CACTUS and QUASAR 3 Groups

Acronym

SCOT - Short Course Oncology Therapy

Study objectives

The study aims to ascertain whether 3 months of treatment is as efficacious as 6 months with the further aim of providing robust evidence on the cost-effectiveness of reducing the duration of adjuvant therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Glasgow Ethics Committee 1, 21/01/2008, ref: 07/S08703/136

All other centres will seek ethics approval before recruitment of the first participant

Study design

Open randomized controlled multi-centre non-inferiority trial incorporating a nested methodology study and an initial pilot period

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Participating information sheet no longer available

Health condition(s) or problem(s) studied

Colorectal cancer

Interventions

Control arm - 6 months of XELOX/FOLFOX chemotherapy

Experimental arm - 3 months of XELOX/FOLFOX chemotherapy

The treatment regimen will be either:

1. Oxaliplatin/capecitabine (XELOX), which is a 3 weekly cycle OR;
2. Oxaliplatin/5-fluorouracil (5 FU) (FOLFOX), which is a 2 weekly cycle

Depending on which arm the patient draws and which regimen they are given will establish the number of cycles, for example on the control arm receiving XELOX regimen patient would receive 8 cycles at 3 weekly intervals or if receiving FOLFOX regimen on control arm would receive 12 cycles at 2 weekly intervals.

The same would apply for the experimental arm, for example a patient receiving XELOX regimen would receive 4 cycles at 3 weekly intervals or if receiving FOLFOX regimen 6 cycles at 2 weekly intervals.

XELOX regimen dosage details: three weeks (21 day cycle) oxaliplatin 130 mg/m² intravenous (IV) over 2 hours on day one, capecitabine 1000 mg/m² on day 1 to day 14, twice daily (bid) (oral).

FOLFOX regimen dosage details: 2 weeks (14-day cycle) oxaliplatin 85 mg/m² IV over 2 hours on day 1, 5 FU 400 mg/m² on day 1 bolus injection, 5 FU 600 mg/m² on day 2 IV over 22 hours, 5 FU 400 mg/m² on day 3 bolus injection, 5 FU 600 mg/m² day 3 IV over 22 hours.

Clinical follow-up once treatment is complete will be monthly for 3 months (experimental arm only), 3 monthly until month 12 (end of year 1), 6-monthly until month 24 (end of year 2), then annually thereafter. The maximum duration of follow-up will be 7 years.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Oxaliplatin/capecitabine (XELOX), Oxaliplatin/5-fluorouracil (5 FU) (FOLFOX)

Primary outcome measure

Non-inferiority question:

Disease free survival (defined as time from randomisation to recurrence, development of new colorectal cancer or death from any cause).

Timing of randomisation question:

Projected probability of study completing recruitment with at most a 4-month overrun.

Secondary outcome measures

Non-inferiority question:

1. Overall survival
2. Cost effectiveness
3. Toxicity
4. Quality of life

Timing of randomisation question:

Compliance rate with allocated treatment duration.

For the purposes of this study patients will be followed up with clinical examination and CEA at 3-monthly intervals until month 12 (end of year 1) then 6-monthly until month 24 (end of year 2). Computed Tomography (CT) scanning will be performed at six-monthly intervals for 2 years and colonoscopy per individual centre protocol. In years 3 to 5 patients will be reviewed at yearly intervals. Investigations will be performed at other times as clinically indicated.

European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30) questionnaire and EORTC QLQ-CR29 (a colorectal module) will be administered prior to randomisation and prior to each treatment cycle. In addition quality of life will be assessed monthly in the experimental arm (3-month arm) for the three months post treatment; there will be follow-up quality of life assessments in both arms at 9 and 12 months of study.

Neurotoxicity will be assessed at the same time points as quality of life using the Functional Assessment of Cancer Therapy/Gynaecologic Oncology Group - Neurotoxicity (FACT/GOG Ntx) questionnaire.

In addition to the disease specific EORTC QOL questionnaires, the generic EuroQoL (EQ-5D) questionnaire will be employed to facilitate the calculation of quality of life utilities suitable for the economic analysis. This will be administered at the same frequency as the EORTC QOL questionnaires.

Overall study start date

01/08/2005

Completion date

30/11/2017

Eligibility

Key inclusion criteria

Current inclusion criteria as of 10/07/2014:

1. Fully resected stage III colorectal cancer or high-risk stage II disease (defined as T4 disease, perforation, obstruction, less than 10 nodes examined, poorly differentiated histology or venous invasion)
2. No evidence of metastatic disease
3. Within 11 weeks of surgery
4. World Health Organisation Performance Status (WHO PS) equals zero or one
5. Greater than or equal to 18 years of age
6. Life expectancy greater than 5 years
7. Written informed consent
8. Normal Carcinoembryonic Antigen (CEA)
9. Patients with rectal cancer will be eligible unless they have had pre-op (chemotherapy) radiotherapy or are scheduled for post-op (chemotherapy) radiotherapy. Such patients must have had Total Mesorectal Excision (TME) surgery with negative (RO) resection margins

Previous inclusion criteria:

1. Fully resected stage III colorectal cancer or high-risk stage II disease (defined as T4 disease, perforation, obstruction, less than 10 nodes examined, poorly differentiated histology or venous invasion)
2. No evidence of metastatic disease

3. Within eight weeks of surgery
4. World Health Organisation Performance Status (WHO PS) equals zero or one
5. Greater than or equal to 18 years of age
6. Life expectancy greater than five years
7. Written informed consent
8. Normal Carcinoembryonic Antigen (CEA)
9. Patients with rectal cancer will be eligible unless they have had pre-op (chemotherapy) radiotherapy or are scheduled for post-op (chemotherapy) radiotherapy. Such patients must have had Total Mesorectal Excision (TME) surgery with negative (RO) resection margins

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

6144

Total final enrolment

6088

Key exclusion criteria

1. Previous chemotherapy
2. Previous abdomino-pelvic radiotherapy
3. Moderate/severe renal impairment (Glomerular Filtration Rate [GFR] less than 30 ml/min)
4. Absolute neutrophil count less than 1.5×10^9
5. Platelet count less than 100×10^9
6. Haemoglobin less than 9 g/dl
7. Liver function tests greater than 2.5 Upper Limit of Normal (ULN)
8. Clinically significant cardiovascular disease
9. Pregnancy/lactation or of childbearing potential not using adequate contraception
10. Previous malignancy
11. Known Dihydropyrimidine Dehydrogenase (DPD) deficiency

In addition, for the 3-month randomisation point, only patients deemed to be fit to continue treatment will be randomised.

Date of first enrolment

09/05/2008

Date of final enrolment

29/11/2013

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

The Beatson West of Scotland Cancer Centre

Glasgow

United Kingdom

G12 0YN

Sponsor information

Organisation

NHS Greater Glasgow and Clyde

Sponsor details

Research and Development Central Office

The Tennent Institute

1st Floor

Western Infirmary

38 Church Street

Glasgow

Scotland

United Kingdom

G11 6NT

Sponsor type

Government

Website

<http://www.nhsggc.org.uk/r&d>

ROR

<https://ror.org/05kdz4d87>

Organisation

University of Glasgow

Sponsor details

University Avenue
Glasgow
Scotland
United Kingdom
G12 8QQ

Sponsor type

University/education

Website

<http://www.gla.ac.uk/>

ROR

<https://ror.org/00vtgdb53>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) (ref: G0601705)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Publications to a high-impact peer reviewed journal have recently been submitted, awaiting outcome. Once the primary paper has been published, a summary of the results will be published on the CancerHelp website (<http://cancerhelp.cancerresearchuk.org/>).

Intention to publish date

30/11/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018		Yes	No
Results article	results	01/12/2019	20/12/2019	Yes	No
Plain English results			25/10/2022	No	Yes
Other publications	Post hoc analysis	12/06/2024	13/06/2024	Yes	No