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

Submission date 10/07/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/08/2007	**Overall study status** Completed	
Last Edited 13/06/2024	**Condition category** Cancer	

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

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Additional identifiers

Clinical Trials Information System (CTIS)
2007-003957-10

ClinicalTrials.gov (NCT)
NCT00749450

Protocol serial number
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

Study type(s)
Treatment

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/m^2 intravenous (IV) over 2 hours on day one, capecitabine 1000 mg/m^2 on day 1 to day 14, twice daily (bid) (oral).

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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 x 10^9
5. Platelet count less than 100 x 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
United Kingdom

Scotland

Study participating centre
The Beatson West of Scotland Cancer Centre
Glasgow
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G12 0YN

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

ROR
https://ror.org/05kdz4d87

Organisation
University of Glasgow

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

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
Other publications	Post hoc analysis	12/06/2024	13/06/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			25/10/2022	No	Yes