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A Prospective Randomised Multicentre Phase III Clinical Trial Comparing the Effects of Panorex Injection Plus 5-Fluorouracil (5-FU)/Leucovorin versus 5-Fluorouracil/Leucovorin versus PANOREX alone, in patients with Surgically resected Stage III (Dukes C) Carcinoma of the Colon

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 30/03/2020	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number

MA2B3002

Study information

Scientific Title
A Prospective Randomised Multicentre Phase III Clinical Trial Comparing the Effects of Panorex Injection Plus 5-Fluorouracil (5-FU)/Leucovorin versus 5-Fluorouracil/Leucovorin versus PANOREX alone, in patients with Surgically resected Stage III (Dukes C) Carcinoma of the Colon

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Colon cancer

Interventions
1. Arm 1: Panorex (900 mg) (1 x 500 mg 5-FU, 4 x 100 mg Luecovorin)
2. Arm 2: 5-FU - 425 mg/m2/d x 5 days for six courses; Leucovorin - 20 mg.m2/day x 5 days for six courses
3. Arm 3: Panorex alone (900 mg)

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
edrecolomab (or Panorex)

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
12/03/1999

Eligibility

Key inclusion criteria
1. Histopathologically documented stage III (Dukes C) colon cancer
2. Less than 6 weeks since surgical removal of the tumour
3. Tumour-free margin of resection
4. Total resection of tumour by laparoscopy is an exclusion
5. Age >18: World Health Organisation (WHO) performance status of 0, 1 or 2: Life expectancy at least 12 months
6. Adequate haematological, hepatic and renal function
7. No metastatic, recurrent, locally advanced cancer or previous history of cancer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1998

Date of final enrolment
12/03/1999

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Glaxo Wellcome (UK)

ROR
https://ror.org/01xsqw823

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary