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

# Plain English summary of protocol

Not provided at time of registration

### Contact information

## Type(s)

Scientific

#### Contact name

Dr - -

#### Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

# Additional identifiers

Protocol serial number

# 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