

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/03/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1998

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Glaxo Wellcome (UK)

Sponsor details

Stockley Park West

Uxbridge, Middlesex

United Kingdom

UB11 1BT

Sponsor type

Industry

Website

<http://uk.gsk.com>

ROR

<https://ror.org/01xsqw823>

Funder(s)

Funder type

Industry

Funder Name

GlaxoSmithKline

Alternative Name(s)

GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration