

Pan-European Trials in Adjuvant Colon Cancer. PETACC-1: The Value of Tomudex Relative to Standard Leucovorin Modulated Bolus 5-Fluorouracil (5-FU)

Submission date 19/08/2002	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/08/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/07/2014	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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Additional identifiers

Protocol serial number

PETACC-1

Study information

Scientific Title

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)

Not Specified

Health condition(s) or problem(s) studied

Colon

Interventions

1. Standard Arm: LV 20 mg/m² iv bolus followed by 425 (or 370) mg/m² 5-FU iv bolus.
2. Experimental Arm: Tomudex 3.0 mg/m² 15 min iv infusion on day 1, repeated on day 22 for eight cycles (24 weeks). Day 1-21 is one cycle.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

16/07/1999

Eligibility**Key inclusion criteria**

Patients with Dukes C Colon Cancer who have had a curative resection within 56 days and are fit for both treatments. Inclusion:

1. Written informed consent
2. Histologically confirmed Dukes C colon cancer

3. Curative radical resection within the last 56 days
4. Aged 18 years or over
5. World Health Organisation (WHO) performance status 0, 1

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1998

Date of final enrolment

16/07/1999

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information**Organisation**

AstraZeneca Clinical Research Group (UK)

ROR

<https://ror.org/04r9x1a08>

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca Pharmaceuticals (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2008		Yes	No