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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 14/07/2014	**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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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
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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