ISRCTN72194324 https://doi.org/10.1186/ISRCTN72194324

# 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**<br>19/08/2002 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>19/08/2002 | **Overall study status**<br>Completed | |
| **Last Edited**<br>14/07/2014 | **Condition category**<br>Cancer | |

**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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Not Specified

### Participant information sheet

### 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 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
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

### Age group
Adult

### Lower age limit
18 Years

### 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
16/07/1999

## Locations

### Countries of recruitment
England

United Kingdom

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

# Sponsor information

**Organisation**
AstraZeneca Clinical Research Group (UK)

**Sponsor details**
10 Logie Mill
Beaverbank Office Park
Lovie Green Road
Edinburgh
United Kingdom
EH7 4HG

**Sponsor type**
Industry

**Website**
http://www.astrazeneca.co.uk

**ROR**
https://ror.org/04r9x1a08

# Funder(s)

**Funder type**
Industry

**Funder Name**
AstraZeneca Pharmaceuticals (UK)

# 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

## Study outputs

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