ISRCTN99195212 https://doi.org/10.1186/ISRCTN99195212

# An open, randomised, multicentre trial of Tomudex (ZD1694) versus 5-Fluorouracil (5-FU) and Leucovorin (LV) in patients with advanced colorectal carcinoma

**Submission date**
19/08/2002

**Recruitment status**
No longer recruiting

**Registration date**
19/08/2002

**Overall study status**
Completed

**Last Edited**
11/01/2016

**Condition category**
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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**
COLO2

## Study information

**Scientific Title**

An open, randomised, multicentre trial of Tomudex (ZD1694) versus 5-Fluorouracil (5-FU) and Leucovorin (LV) in patients with advanced colorectal carcinoma

### 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
Open randomised multicentre trial

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Advanced colorectal carcinoma

### Interventions
1. Treatment A: Tomudex, a single dose repeated every three weeks until disease progression, unacceptable toxicity or proof of no clinical benefit to the patient.
2. Treatment B: Leucovorin followed by 5-fluorouracil daily for five days, repeated at week four, week eight and every five weeks thereafter until disease progression, unacceptable toxicity or proof of no clinical benefit to the patient.

### Intervention Type
Drug

### Phase
Phase III

### Drug/device/biological/vaccine name(s)
Raltitrexed (Tomudex®), leucovorin, 5-fluorouracil

### Primary outcome(s)
Not provided at time of registration

### Key secondary outcome(s))
Not provided at time of registration

### Completion date
31/12/2001

## Eligibility

### Key inclusion criteria
1. Microscopically confirmed adenocarcinoma of the colon or rectum
2. Locally advanced, or metastatic (Dukes stage D) disease for which no curative therapy is available
3. Aged over 18 years
4. One or more measurable or evaluable lesions
5. World Health Organisation (WHO) performance status 0-2
6. Life expectancy of at least three months
7. Adequate bone marrow and liver function

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Previous systemic chemotherapy for colorectal cancer
2. Concomitant use of any systemic anticancer therapy
3. Adjuvant chemotherapy within the last 12 months
4. Concomitant administration of folic acid other than the trial therapy
5. Known brain metastases
6. Previous or concurrent malignancies at other sites, except adequately treated in-situ carcinoma of the cervix uteri and basal or squamous cell carcinoma of the skin
7. Other medical contraindications to treatment

### Date of first enrolment
01/01/2000

### Date of final enrolment
31/12/2001

## Locations

### Countries of recruitment
United Kingdom

England

**Study participating centre**
**MRC Clinical Trials Unit**
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

**Alternative Name(s)**
AstraZeneca PLC, Pearl Therapeutics, AZ

**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**

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |