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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
19/08/2002	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
19/08/2002	Completed	Results
Last Edited	Condition category	Individual participant data
11/01/2016	Cancer	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

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# 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

## Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

# 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**

# Drug/device/biological/vaccine name(s)

Raltitrexed (Tomudex®), leucovorin, 5-fluorouracil

#### Primary outcome measure

Not provided at time of registration

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/01/2000

#### 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** 

# Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

# Target number of participants

Not provided at time of registration

#### 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

England

**United Kingdom** 

Study participating centre MRC Clinical Trials Unit 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

# Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics

# **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