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	Prospectively registered
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, AZ

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