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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
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Contact details
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United Kingdom
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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