ISRCTN41540878 https://doi.org/10.1186/ISRCTN41540878

A multicentre study using the chemotherapy combination of bi-monthly Xeloda and Eloxatin, with the addition of Avastin, in patients with advanced colorectal cancer

Submission date
01/05/2006

Recruitment status
No longer recruiting

Registration date
15/05/2006

Overall study status
Completed

Last Edited
02/06/2015

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ctnz.auckland.ac.nz

Contact information

Type(s)
Scientific

Contact name
Prof Michael Findlay

Contact details
Cancer Trials New Zealand (CTNZ)
Rm 3443 Building 503
Faculty of Medical and Health Sciences
University of Auckland
Private Bag 92019
Auckland
New Zealand
1003
+64 (0)9 373 7599 ext 82005
mp.findlay@auckland.ac.nz

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CTNZ _05_6

Study information

Scientific Title
A multicentre study using the chemotherapy combination of bi-monthly Xeloda and Eloxatin, with the addition of Avastin, in patients with advanced colorectal cancer

Acronym
XEN study

Study objectives
Bi-monthly dose intensified capecitabine (Xeloda) and oxaliplatin (Eloxatin) with concurrent bevacizumab (Avastin) will be a tolerable, effective, drug combination in the treatment of advanced colorectal cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
New Zealand Multi-Regional Ethics Committee, 20/04/2006, ref: MEC/06/04/041

Study design
Multi-centre phase IV study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Advanced colorectal cancer

Interventions

Dose intensified capecitabine days 1-7, oxaliplatin IV day 1 (diCapeOx), repeat every 14 days plus concurrent bevacizumab IV day 1, repeat every 14 days. Treatment will continue until progression, unacceptable toxicity or patient request.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Capecitabine (Xeloda), oxaliplatin (Eloxatin), bevacizumab (Avastin)

Primary outcome measure
Progression free survival

Secondary outcome measures
1. Proportion of patients who receive at least 75% of the planned dose
2. Rate of grade 3 and 4 neutropenia
3. Grade 3 and 4 toxicity rates
4. Tumour response rates
5. Survival

Overall study start date
26/05/2006

Completion date
31/03/2009

Eligibility

Key inclusion criteria
1. Histological/cytological confirmation of colorectal cancer
2. Locally recurrent or metastatic disease
3. Patient performance status (Eastern Cooperative Oncology Group (ECOG) 0-1
4. Creatinine clearance greater than or equal to 50 ml/min assessed by Cockroft-Gault formula. If Cockroft-Gault formula yields less than 50 ml/min, direct measurement of creatinine clearance or glomerular filtration rate may be made according to local practice. Direct measurement must be greater than 50 ml/min.
5. Urine dipstick of proteinuria <2+. Patients discovered to have ≥2+ proteinuria on dipstick urinalysis at baseline, should undergo a 24-hour urine collection and must demonstrate ≤1 g of protein per 24 hr

6. Laboratory values as follows:
Haematology:
a. Absolute neutrophil count (ANC) >1.5 x 10^9 /l
b. Platelet count >100 x 10^9 /l
c. Haemoglobin >9 g/dl (may be transfused to maintain or exceed this level)
d. International normalized ratio (INR) <1.5; arterial pulse propagation time (APPT) <1.5 x upper limit of normal (ULN)

Biochemistry:
a. Total bilirubin <1.5 x ULN; serum total bilirubin <30 µmol/l
b. Aspartate aminotransferase (AST) or alanine transaminase (ALT) <2.5 x ULN in patients without liver metastases; <5 x ULN in patients with liver metastases
c. Serum creatinine <2.0 mg/dl or 177 µmol/l (see creatinine clearance criteria above)
7. Age ≥18years
8. Accessible for treatment and follow up
9. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Previous systemic therapy (excluding adjuvant treatment) for advanced colorectal cancer
2. Less than six months following last dose of adjuvant systemic therapy
3. Current or recent (within the 30 days prior to starting study treatment) treatment of another investigational drug or participation in another investigational drug study
4. Unsuitable for treatment with capecitabine (e.g. fluorouracil [5FU] side effects suggestive of dihydropyrimidine dehydrogenase deficiency; gastrointestinal [GI] disease precluding oral therapy)
5. Serious uncontrolled infection
6. Unsuitable for treatment with oxaliplatin (e.g. significant neuropathy i.e. greater than grade 1 Common Toxicity Criteria [CTC] criteria)
7. Brain and/or leptomeningeal disease
8. Pregnant or breastfeeding women
9. Concurrent anticancer therapy (any radiation must be completed at least four weeks before registration)
10. Other malignancy in previous five years except adequately treated basal cell or squamous cell carcinoma of skin or in-situ carcinoma of the cervix
11. Treatment with antiviral agent sorivudine, or related compounds such as brivudine
12. Clinically significant and active cerebral vascular disease and/or cerebral vascular accident ≤6 months prior to registration, myocardial infarction ≤1 year prior to registration, uncontrollable hypertension whilst receiving chronic medication, unstable angina, New York Heart Association (NYHA) grade 2 or greater congestive heart failure or serious cardiac arrythmia requiring medication
13. Major surgery within 28 days prior to treatment commencement or anticipation of the need for major surgical procedure during the course of the study
14. Current or recent (within 10 days prior to study treatment start) use of full-dose oral or parenteral anticoagulants for therapeutic purposes

15. Chronic daily treatment with aspirin (>325 mg/day)
16. Serious, non-healing wound, ulcer, or bone fracture
17. Evidence of other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates use of an investigational drug or patient at high risk from treatment complications
18. Patients with known allergy to Chinese hamster ovary cell proteins or other recombinant human or humanized antibodies or to any excipients of bevacizumab formulation or to any other study drugs
19. Patients unable to swallow oral tablets

Date of first enrolment
26/05/2006

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
New Zealand

Study participating centre
Cancer Trials New Zealand (CTNZ)
Auckland
New Zealand
1003

Sponsor information

Organisation
Cancer Trials New Zealand (CTNZ)

Sponsor details
Room 3443 Building 503
Faculty of Medical and Health Sciences
University of Auckland
Private Bag 92019
Auckland
New Zealand
1003
+64 (0)9 373 7599 ext 83585
greta.riley@auckland.ac.nz

Sponsor type
Research organisation

Website
http://www.ctnz.auckland.ac.nz

Funder(s)

Funder type
Industry

Funder Name
Research grant from Roche Products (NZ) Ltd

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	02/10/2014		Yes	No