Prospective randomised clinical trial phase II: 5fluorouracil/folinic acid (5-FU/FA) and irinotecan versus combination cepecitabin and irinotecan in patients with metastatic colorectal cancer as first line treatment

Recruitment status No longer recruiting	Prospectively registered		
	Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category Cancer	[] Individual participant data		
	Overall study status Completed Condition category		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Janja Ocvirk

Contact details

Institute of Oncology Ljubljana Zaloska 2 Ljubljana Slovenia 1000

Additional identifiers

Protocol serial number

Slovenian Research Agency (ARRS) ref: L3-6059

Study information

Scientific Title

Prospective randomised clinical trial phase II: 5-fluorouracil/folinic acid (5-FU/FA) and irinotecan versus combination cepecitabin and irinotecan in patients with metastatic colorectal cancer as first line treatment

Study objectives

There will be no statistically significant differences in efficacy, safety and survival of XELIRI regimen compared to standard FOLFIRI regimen in neoadjuvant setting of patients with unresectable liver-only metastases of colorectal cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Medical Ethics Committee, Ministry of Health, 09/12/2003, ref: 135/12/03

Study design

Prospective randomised single-centre phase II trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Inoperable liver metastases of colorectal cancer

Interventions

The patients were randomised to either group A (XELIRI) or group B (FOLFIRI) (1:1 randomisation).

XELIRI regimen consisted of irinotecan (i.v.) 250 mg/m² given on Day 1 and capecitabine (oral) 1,000 mg/m² twice daily on Day 2-15, every 21 days.

FOLFIRI regimen consisted of irinotecan (i.v.) 180 mg/m^2, 5-fluorouracil (5-FU) (i.v.) 400 mg/m^2, leucovorin (LV) (i.v.) 200 mg/m^2, 5-FU (i.v.) 2,400 mg/m^2 (46-h infusion), all given on Day 1, every 14 days.

The patients in both groups received premedication with dexamethason 20 mg (intravenous [i. v.]), granisetron 1 mg i.v. and diazepam 10 mg i.v. on Day 1 of each chemotherapy cycle.

Planned treatment duration with chemotherapy was 24 weeks in both arms. In cases where the liver metastases became operable in response to the initial (neoadjuvant or preoperative) chemotherapy, radical (R0) resection of the metastases was performed.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Cepecitabin and Irinotecan

Primary outcome(s)

During the therapy, the following were assessed at baseline, 3 and 6 months, thereafter followup was every 3 months until progression of the disease (no limit on the maximum duration of follow-up):

- 1. Response rate: Response Evaluation Criteria in Solid Tumors (RECIST)
- 2. Rate of radical surgical resection (R0 resection)

Key secondary outcome(s))

During the therapy, the following were assessed at baseline, 3 and 6 months, thereafter followup was every 3 months until progression of the disease (no limit on the maximum duration of follow-up):

- 1. Safety
- 2. Progression-free survival (PFS)
- 3. Overall survival (OS)

Completion date

31/12/2006

Eligibility

Key inclusion criteria

- 1. Both males and females, age between 18-75 years
- 2. World Health Organization (WHO) performance status 0-1
- 3. Inoperable liver metastases of colorectal adenocarcinoma
- 4. No prior chemotherapy for metastatic disease
- 5. >6 months since adjuvant treatment
- 6. At least one measurable lesion visible on spiral computerised tomography (CT)
- 7. Adequate haematological, hepatic and renal function

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Key exclusion criteria

- 1. Metastases outside of the liver
- 2. Local recurrence of colorectal cancer
- 3. Bilirubin >2 x upper limit of normal (ULN), aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >5 x ULN
- 4. Clinical signs of cardiac decompensation
- 5. Ischaemic heart disease
- 6. Inflammatory bowel disease
- 7. History of other cancer
- 8. Participation in other study protocol

Date of first enrolment

01/01/2004

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Slovenia

Study participating centre Institute of Oncology Ljubljana

Ljubljana Slovenia 1000

Sponsor information

Organisation

Ministry of Higher Education, Science and Technology (Slovenia)

ROR

https://ror.org/0452h9305

Funder(s)

Funder type

Government

Funder Name

Results and Publications

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	22/04/2009		Yes	No