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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

Submission date 13/08/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/08/2008	**Overall study status** Completed	
Last Edited 23/07/2015	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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/m^2 given on Day 1 and capecitabine (oral) 1,000 mg/m^2 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 measure
During the therapy, the following were assessed at baseline, 3 and 6 months, thereafter follow-up 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)

Secondary outcome measures
During the therapy, the following were assessed at baseline, 3 and 6 months, thereafter follow-up 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)

Overall study start date
01/01/2004

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
100

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
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Sponsor information

Organisation
Ministry of Higher Education, Science and Technology (Slovenia)

Sponsor details
Kotnikova 38
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Sponsor type
Government

Website
http://www.vlada.si/?gr1=min&gr2=minSzt&gr3=&gr4=&id=&lng=eng

ROR
https://ror.org/0452h9305

Funder(s)

Funder type
Government

Funder Name
Ministry of Higher Education, Science and technology (Slovenia)

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	22/04/2009		Yes	No