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Prospective randomised phase II clinical trial of epirubicin, cisplatin, continuous infusional 5-fluorouracil (ECF) versus epirubicin, cisplatin and capecitabin (ECX) in patients with advanced gastric cancer

Submission date 03/09/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/11/2008	**Overall study status** Completed	
Last Edited 17/07/2012	**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: P3-0321

Study information

Scientific Title

Study objectives
Null hypothesis: There will be no statistically significant difference in efficacy, safety and survival of ECX (epirubicin, cisplatin, capecitabin) regimen compared to ECF (epirubicin, cisplatin, continuous infusional 5-fluorouracil) regimen in patients with advanced gastric cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National Medical Ethics Committee, Ministry of Health. Date of approval: 11/06/2002 (ref: 92 /06/02)

Study design
Phase II, randomised, single-centre 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
Advanced gastric cancer

Interventions
This trial took place at the Institute of Ljubljana (single-centre trial).

Patients were randomised to ECF or ECX chemotherapy group in equal numbers:

ECF consisted of epirubicin 50 mg/m^2, cisplatin 60 mg/m^2 on Day 1 by intravenous injection, 5-FU 200 mg/m^2/day was administrated by continuous infusion on Day 1-14 of each cycle. Cycle was repeated every 3 weeks.

In ECX combination epirubicin 50 mg/m^2 and cisplatin 60 mg/m^2 were administrated on Day 1 by intravenous injection. Capecitabine 825 mg/m^2 twice daily was administrated orally on Day 1-14. Cycle was repeated every 3 weeks.

Treatment was continued until disease progression, unacceptable toxicity occurred or the patient refused further treatment.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Epirubicin, cisplatin, 5-fluorouracil, capecitabin

Primary outcome measure
Response rate, assessed by the Response Evaluation Criteria in Solid Tumors (RECIST)

The primary and secondary outcomes were assessed at baseline, 3 and 6 months during therapy, then follow-up was performed every 3 months until progression of disease.

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

The primary and secondary outcomes were assessed at baseline, 3 and 6 months during therapy, then follow-up was performed every 3 months until progression of disease.

Overall study start date
01/01/2003

Completion date
31/03/2007

Eligibility

Key inclusion criteria
1. Both males and females, age 18 years or older
2. Histologically confirmed advanced gastric cancer
3. Performance status of 0-2
4. Adequate bone marrow function
5. Adequate renal, hepatic function
7. Normal cardiac function
8. Estimated life expectancy more than 3 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Performance status more than 2
2. Patients not recovered from operation
3. Patients with unresolved intestinal obstruction
4. Malabsorption syndrome
5. Pregnancy
6. Breastfeeding or childbearing potential without using adequate contraception
7. Cardiovascular diseases (New York Heart Association [NYHA] III-IV)
8. Impaired renal function
9. Liver diseases
10. Active hepatitis (hepatitis B, hepatitis C)
11. HIV positive
12. Other active infection

Date of first enrolment
01/01/2003

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
Slovenia

Study participating centre
Institute of Oncology Ljubljana
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.mvzt.gov.si/en

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	01/06/2012		Yes	No