

# 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

<b>Submission date</b> 03/09/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/11/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/07/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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)

### Primary study design

Interventional

### Study design

Phase II, randomised, single-centre trial

### Study type(s)

Treatment

### 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<sup>2</sup>, cisplatin 60 mg/m<sup>2</sup> on Day 1 by intravenous injection, 5-FU 200 mg/m<sup>2</sup>/day was administered by continuous infusion on Day 1-14 of each cycle. Cycle was repeated every 3 weeks.

In ECX combination epirubicin 50 mg/m<sup>2</sup> and cisplatin 60 mg/m<sup>2</sup> were administered on Day 1 by intravenous injection. Capecitabine 825 mg/m<sup>2</sup> twice daily was administered 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(s)**

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.

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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

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**

Ministry of Higher Education, Science and Technology (Slovenia)

# 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?
<a href="#">Results article</a>	results	01/06/2012		Yes	No