

Phase II trial of combination therapy with oxaliplatin and capecitabine in patients with advanced oesophageal cancer

Submission date 27/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/08/2021	Condition category 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
EMC 03-048, Trial NL448 (NTR488)

Study information

Scientific Title

Phase II trial of combination therapy with oxaliplatin and capecitabine in patients with advanced oesophageal cancer

Acronym

Xelox

Study objectives

For patients with metastatic or local-regional unresectable oesophageal carcinoma there is no alternative treatment. In this trial it is studied whether combination chemotherapy with oxaliplatin and capecitabine prolongs survival and improves quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received by the Medical Ethics Board of our hospital (Erasmus MC) on the 27th March 2003 (ref: EMC 03-048).

Study design

Phase II, non-randomised, non-controlled, clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Oesophageal cancer

Interventions

Oxaliplatin 130 mg/m² Intravenous (IV) day one and capecitabine 1000 mg/m² twice daily orally days one to 14 (28 doses) repeated every three weeks.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Oxaliplatin and capecitabine

Primary outcome(s)

1. To evaluate the efficacy as measured by response rate and time to progression of the combination of oxaliplatin and capecitabine to patients with metastatic or local-regional unresectable carcinoma of the oesophagus, oesophagogastric junction and cardia
2. To evaluate the safety of this combination therapy in such a group of patients
3. To evaluate and assess quality of life during treatment

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/10/2005

Eligibility

Key inclusion criteria

1. Metastatic or local-regional unresectable adenocarcinoma or squamous cell carcinoma oesophagus or gastric junction
2. At least one unidimensional measurable lesion greater than 20 mm (conventional), or greater than 10 mm (spiral)
3. World Health Organisation (WHO) grade zero to two
4. Adequate haematological, renal and hepatic functions

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Total final enrolment

51

Key exclusion criteria

1. Prior treatment with oxaliplatin or capecitabine; prior (neo)-adjuvant treatment for metastatic disease is allowed if completed at least six months prior to study start
2. Malabsorption syndrome or inability to take oral medication
3. Pre-existing motor or sensory neurotoxicity greater than grade one
4. Active infection

Date of first enrolment

01/04/2003

Date of final enrolment

01/10/2005

Locations

Countries of recruitment

Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
Erasmus Medical Centre (The Netherlands)

ROR
<https://ror.org/018906e22>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (The Netherlands)

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		17/04/2007	26/08/2021	Yes	No