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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/02/2007	**Overall study status** Completed	
Last Edited 26/08/2021	**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

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).

Primary study design
Interventional

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Oesophageal cancer

Interventions
Oxaliplatin 130 mg/m^2 Intravenous (IV) day one and capecitabine 1000 mg/m^2 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