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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20867

Source
NTR

Brief title
Xelox

Health condition

Esophageal cancer.

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

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 esophagus, esophagogatric 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.

Secondary outcome

N/A

Study description

Background summary

N/A

Study objective

For patients with metastatic or local-regional unresectable esophageal 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.

Study design

N/A

Intervention

Oxaliplatin 130 mg/m2 IV day 1 and capecitabine 1000 mg/m2 twice daily orally days 1-14 (28 doses) repeated every 3 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

Metastatic or local-regional unresectable adenocarcinoma or squamous cell carcinoma esophagus or gastric junction, at least one unidimensional measurable lesion > 20mm (conventional), > 10mm (spiral), WHO 0-2, adequate hematological, renal and hepatic functions.

Exclusion criteria

Prior treatment with oxaliplatin or capecitabine;
prior (neo)adjuvant treatment for metastatic disease is allowed if completed at least 6 months prior to study start. malabsorption syndrome or inability to take oral medication, pre-existing motor or sensory neurotoxicity grade >1, active infection.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-04-2003
Enrollment:	43
Type:	Actual

Ethics review

Positive opinion Date:	15-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL448
NTR-old	NTR488
Other	: EMC 03-048
ISRCTN	ISRCTN07447845

Study results

Summary results
Br J Cancer. 2007 May 7;96(9):1348-52. Epub 2007 Apr 17.