EXPAND (Erbitux in combination with Xeloda and cisplatine in advanced esophago-gastric cancer);Open-label, randomized, controlled, multicenter phase III study investigating cetuximab in combination with capecitabine (Xeloda, X) and cisplatin (P) versus XP alone as first-line treatment for subjects with advanced gastric adenocarcinoma including adenocarcinoma of the gastroesophageal junction.

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To demonstrate superiority of XP chemotherapy regimen plus cetuximab versus XP alone asfirst-line treatment for advanced gastric cancer in terms of PFS. To assess cetuximab + XP versus XP alone with respect to: OS; overall response; QoL; safety.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON31982

Source
ToetsingOnline

Brief title
EXPAND

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
cancer, carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Merck
Source(s) of monetary or material Support: Merck

Intervention

Keyword: carcinoma, gastric cancer

Outcome measures

Primary outcome

Progression Free Survival time.

Secondary outcome

- Overall Survival time

- Best overall response

- Quality of Life questionnaires: EORTC QLQ-C30 and EQ-5D

Study description

Background summary

Please see for background information the protocol section 3, page 18.

Cetuximab in combination with chemotherapy as a 1st-line treatment of advanced gastric
cancer showed promising response rates and encouraging survival data in 3 phase II

studies (see section 3.3) [13, 14, 15]. In the present study, cetuximab will be added to the
XP chemotherapy regimen (oral 5-FU prodrug capecitabine = Xeloda + cisplatin) to demonstrate that addition of cetuximab provides a clinically relevant benefit in this disease
setting.
XP is one of the current standard regimens for 1st-line treatment of advanced gastric cancer [1]. The European Commission has recently approved the XP regimen for
1st-line treatment of advanced gastric cancer. The XP combination regimen has also gained
approval in other countries.

Study objective

To demonstrate superiority of XP chemotherapy regimen plus cetuximab versus XP alone as
first-line treatment for advanced gastric cancer in terms of PFS.

To assess cetuximab + XP versus XP alone with respect to: OS; overall response; QoL; safety.

Study design

Multicenter open-label, randomized, controlled, phase III study. Subjects will be randomized on a 1:1 basis to the following treatment: Group A: Cetuximab q week + XP q 3 weeks, Group B: XP q 3 weeks.

Intervention

Subjects will be randomized on a 1:1 basis to the following treatment: Group A: Cetuximab q week + XP q 3 weeks, Group B: XP q 3 weeks.

Cetuximab: 400 mg/m2 at the first infusion, 250 mg/m2 every week as subsequent infusions, i.v.

XP regimen as 3-week cycles: Capecitabine (Xeloda) 1000 mg/m2 twice daily from evening of D1 until morning of D15, p.o. + cisplatin 80 mg/m2 on D1, i.v.

Study burden and risks

At the start of each cycle, the subject will be admitted to the hospital with an overnight stay and will receive intravenous treatment of 4 hours. The schedule of all assessments is described in the protocol section7, table 7.7. Clinically relevant Adverse Events related to cetuximab are described in the

protocol, section 3.4.7.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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Exclusion criteria

zie pagina 13

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Erbitux
Generic name:	Cetuximab

Ethics review

Approved WMO Date:	10-06-2008
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-11-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	07-04-2009
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-07-2009
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-01-2010
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-07-2010
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2007-004219-75-NL
ClinicalTrials.gov	NCT00678535
CCMO	NL23546.091.08