A Multicenter Phase II Study of Neoadjuvant Docetaxel, Cisplatin and Capecitabine and Protocolized Surgery in Resectable Gastric Cancer
An IKZ-based phase II feasibility study

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This study investigates the feasibility role of neoadjuvant chemotherapy, consisting of docetaxel (Taxotere), cisplatin and capecitabine (Xeloda) (TCX), and protocolized surgery in localized and/or locally advanced resectable gastric cancer (D1extra...

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

Summary

ID

NL-OMON31603

Source
ToetsingOnline

Brief title
DoCCS

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
gastric cancer, gastric carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: gastric cancer, neoadjuvant chemotherapy, surgery

Outcome measures

Primary outcome

- Assessment of the feasibility and toxicity efficacy/response rate

(down-sizing/down-staging) of the combination of 4 courses of

docetaxel/Taxotere*, cisplatin and capecitabine/Xeloda* as neoadjuvant

chemotherapy in resectable localized or locally advanced gastric cancer

- Percentage of patients who completed 4 courses of chemotherapy and proceeded

to surgery

- Surgical quality control in resectable gastric cancer

- Establishment of toxicity and safety profile

- Assessment of the reduction of tumour load with CT (or PET-CT) after

neoadjuvant chemotherapy

Secondary outcome

- Introduction of a D1extra-resection as the standard surgical treatment

- Percentage of complete pathological response

- Percentage of complete pathological resection

- Assessment of quality of life after treatment with neo-adjuvant chemotherapy

and surgery in local or locally advanced gastric carcinoma

Study description

Background summary

Nowadays, the only curative option for localized gastric cancer is a curative radical resection. Prognosis, however, remains poor. Results of the SWOG 9008/INT 0116 Phase III trial and the MAGIC trial have underlined the impetus for (neo)adjuvant treatment strategies in combination with adequate protocolized surgery in localized and/or locally advanced gastric cancer.
In advanced gastric cancer, a combination of docetaxel, cisplatin and 5-FU (DCF) has been shown to be a very attractive option (TAX 325 and SAKK 42/99 studies). Furthermore, the use of an orally bioavailable fluoropyrimidine (capecitabine) in combination with docetaxel and cisplatin would enable patients to be treated without the requirement of an indwelling central venous catheter.

Study objective

This study investigates the feasibility role of neoadjuvant chemotherapy, consisting of docetaxel (Taxotere), cisplatin and capecitabine (Xeloda) (TCX), and protocolized surgery in localized and/or locally advanced resectable gastric cancer (D1extra-resection). Furthermore, response measurement with CT (PET-CT) will be evaluated.

Study design

Phase II prospective descriptive study in 50 patients. Experience toxicity is documented. Quality of surgery is protocolized and guaranteed by consultant surgeons of a surgical quality assurance committee.

Intervention

Every patient included in this study will receive 4 courses of chemotherapy consisting of Taxotere, Xeloda and Cisplatin

Study burden and risks

Patients are treated with 4 courses of chemotherapie. Before each cycle, a venapunction will be carried out to assess if a patient can proceed to the next cylce. On the first day of each cylce, a patient will be admitted to the hospital for intravenous treatment with chemotherapy. Patients will undergo one

extra CT-scan to measure the respons of the tumor-load to chemotherapy. Side-effects can exist of i.e. hairloss, febrile neutropenia, thrombocytopenia, nausea, diarrhoea, hand-foot syndrome, neurotoxicity, skin problems (irritation, rash). Surgery will be a burden for patients, but this is not different from regular therapy for gastric cancer.
We are of the opinion that due to the poor 5-year survival of gastric carcinoma resected with a curative intent there is a necessity for research for other kinds of therapy which can improve survival.

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

Ib-IVa histological proven resectable gastric adenocarcinoma, including gastro-oesophageal junction/cardia carcinoma Siewert 2 and 3

WHO < or equal to 1
Age > or equal to 18 years
No prior radio- or chemotherapy conflicting with the treatment of gastric cancer

Exclusion criteria

Ia gastric cancer
Other histological type than adenocarcinoma
Distant metastases
Inoperable patients
Previous or other current malignancies
Other current serious illness or medical conditions
Pregnant or lactating women

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2008
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Cisplatin
Generic name:	Cisplatin
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Taxotere
Generic name:	Docetaxel
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Xeloda
Generic name:	Capecitabine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	08-02-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-11-2008
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-03-2009
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-03-2009
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20157
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2007-007273-23-NL
CCMO	NL20764.028.07
OMON	NL-OMON20157