A study to investigate the feasibility of chemotherapy prior to surgery and protocolized surgery in resectable stomach cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20157

Source
NTR

Brief title
DoCCS

Health condition

Resectable/curable gastric cancer

Sponsors and support

Primary sponsor: dr K. Bosscha, surgeon
dr J.F.M. Pruijt, oncologist
drs A.E. Dassen, resident in training for surgery
Source(s) of monetary or material Support: No financial support

Intervention

Outcome measures

Primary outcome

1. Feasibility and toxicity/safety profile of the combination of 4 courses of docetaxel/Taxotere, cisplatin and capecitabine/Xeloda as neoadjuvant chemotherapy in resectable localized or locally advanced gastric cancer;

2. Assessment of neoadjuvant chemotherapy-induced tumour response with CT or optional PET-CT;

3. Implementation of a D1extra-resection implementation as protocolized surgery in resectable gastric cancer and rate of successful implementation;

4. Assessment of quality of life after treatment with neo-adjuvant chemotherapy and surgery in local or locally advanced gastric carcinoma.

Secondary outcome

1. Determination of chemotherapy-induced pathological response according to WHO criteria for measurement of response;

2. Determination of pathological resection (R0/R1/R2).

Study description

Background summary

The DoCCS-study is a multicentre, phase II study to investigate the feasibility of neoadjuvant chemotherapy consisting of docetaxel/taxotere, cisplatin and capecitabine/xeloda, followed by gastric resection and D1extra-lymphadenectomy in resectable gastric cancer.

This trial is conducted in the Netherlands.

Study objective

Assessment of feasibility of neoadjuvant chemotherapy consisting of docetaxel, cisplatin and capecitabine in resectable localized gastric cancer (stage Ib-IVa) and the introduction of the D1extra-lymphadenectomy as the standardized surgical treatment modality.

Study design

1. Feasibility and toxicity/safety proflie of chemotherapy: during and after each course of chemotherapy;

2. Assessment of chemotherapy induced tumour response:

A. With CT: between day 76 and 90;

B. With PET-CT: after course 1 between day 14 and 21 and after course 4 between day 76 and 90;

3. Implementation of D1extra-resection and rate of successful implementation: during and after surgery;

4. Assessment of quality of life: before treatment, after completing neoadjuvant chemotherapy, and 6 weeks, 3 and 12 months after surgery;

5. Determination of chemotherapy induced pathological response: during pathological exam;

6. Determination of pathological resection: during pathological exam.

Intervention

Neo-adjuvant chemotherapy consisting of 4 courses of docetaxel/taxotere, cisplatin and capecitabine/xeloda, followed by gastric resection and a D1-extra lymphadenectomy. The D1-extra-lymphadenectomy consists of resecting lymph node stations 3-9 according to the Japanese classification of gastric carcinoma, and depending on location of tumour, an additional resection of lymph node station 1, 2, 10 and 12a.

Contacts

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Eligibility criteria

Inclusion criteria

1. Ib-IVa histological proven resectable gastric adenocarcinoma, including gastro-

oesophageal junction/cardia carcinoma;

2. Siewert 2 and 3;

3. WHO 1 or ASA 1 or 2;

4. Age 18 years and older;

5. No prior radio- or chemotherapy conflicting with the treatment of gastric cancer;

6. Haematology/Renal function/Liver function within designated range;

7. Patient’s consent form obtained, signed and dated before beginning specific protocol procedures;

8. Expected patient’s compliance with treatment, management of toxicity and scheduled follow-up.

Exclusion criteria

1. Inoperable patients;

2. Previous or other current malignancies, with the exception of adequately treated in situ carcinoma of the cervix uteri or non-melanoma skin cancer;

3. Other current serious illness or medical conditions:

A. Severe cardiac illness (NYHA class III-IV);

B. Significant neurologic or psychiatric disorders;

C. Uncontrolled infections;

D. Active DIC;

E. Other serious underlying medical conditions that could impair the ability of the patient to participate in the study.

4. Known hypersensitivity to Docetaxel/Taxotere (or any drug formulated with Polysorbate-80), or Cisplatin or Capecitabine/Xeloda or 5-FU;

5. Definite contraindications for the use of corticosteroids;

6. Use of immunosuppressive or antiviral drugs;

7. Any other experimental drugs within a 4-week period prior to start of neoadjuvant chemotherapy and throughout the study period;

8. Pregnant or lactating women;

9. Patients with reproductive potential not implementing adequate contraceptive measures.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-06-2008
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-04-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 31603
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2181
NTR-old	NTR2306
CCMO	NL20764.028.07
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON31603

Study results

Summary results
N/A