Protocol Registration Receipt
10/21/2011

A Multicenter Phase II Study of Neoadjuvant Docetaxel, Cisplatin and Capecitabine and Protocolized Surgery in Resectable Gastric Cancer (DoCCS)

This study is currently recruiting participants.
Verified by Anneriet Dassen, Jeroen Bosch Ziekenhuis, October 2011

Sponsor:	Jeroen Bosch Ziekenhuis
Collaborators:	Eindhoven Cancer Registry
Information provided by (Responsible Party):	Anneriet Dassen, Jeroen Bosch Ziekenhuis
ClinicalTrials.gov Identifier:	

Purpose

The purpose of this study is to determine the feasibility of chemotherapy, consisting of docetaxel, cisplatin and capecitabine given prior to surgery for stomach cancer. Furthermore, an extended type of removal of lymph nodes will be implemented.

Condition	Intervention	Phase
Gastric Cancer	Drug: Docetaxel Drug: cisplatin Drug: Capecitabine Procedure/Surgery: D1extra-resection	Phase 2

Study Type: Interventional
Study Design: Treatment, Single Group Assignment, Open Label, N/A, Safety/Efficacy Study

Further study details as provided by Anneriet Dassen, Jeroen Bosch Ziekenhuis:

Primary Outcome Measure:

- Feasibility and toxicity/safety profile of the combination of 4 courses of docetaxel, cisplatin and capecitabine as neoadjuvant chemotherapy and standardized surgery in resectable localized or locally advanced gastric cancer [Time Frame: 18 weeks] [Designated as safety issue: Yes]
  Patients receive every 3 weeks a cycle of chemotherapy, in total 4 cylcles will be given. Surgery will be performed approximately 6 weeks after the last cycle.

Secondary Outcome Measures:

- Implementation of the D1extra-resection as protocolized surgery in resectable gastric cancer and rate of successful implementation [Time Frame: 30 days] [Designated as safety issue: Yes]

Estimated Enrollment: 50
Study Start Date: June 2008
Estimated Study Completion Date: November 2012
Estimated Primary Completion Date: November 2012

Number of arms: 1
Intervention Details:

Drug: Docetaxel
60 mg/m2, 1 gift every 3 weeks, in total 4 gifts

Drug: cisplatin
60 mg/m2, one gift every three weeks, in total 4 gift

Drug: Capecitabine
1875 mg/m2 in two equally divided doses day 1-14, repeated every three weeks, in total 4 cycles

Procedure/Surgery: D1extra-resection
An extended lymphadenectomy compared to a D1 resection for gastric cancer

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both

Inclusion Criteria:

- Ib-IVa histological proven resectable gastric adenocarcinoma, including gastro-oesophageal junction/cardia carcinoma Siewert 2 and 3
- ASA 2 or less
- Age 18 years or more
- No prior radio- or chemotherapy conflicting with the treatment of gastric cancer
- Haematology/Renal function/Liver function within designated range
- Patient's consent form obtained, signed and dated before beginning specific protocol procedures
- absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial
- before patient registration/randomization, written informed consent must be given according to GCP, WMO

and local regulations.

Exclusion Criteria:

- Previous or other current malignancies, with the exception of adequately treated in situ carcinoma of the cervix uteri or non-melanoma skin cancer
- Other current serious illness or medical conditions
- Severe cardiac illness (NYHA class III-IV)
- Significant neurologic or psychiatric disorders
- Uncontrolled infections
- Active DIC
- Other serious underlying medical conditions that could impair the ability of the patient to participate in the study
- Known hypersensitivity to docetaxel (or any drug formulated with Polysorbate-80), or cisplatin or capecitabine or 5-FU
- Definite contraindications for the use of corticosteroids
- Use of immunosuppressive or antiviral drugs
- Any other experimental drugs within a 4-week period prior to start of neoadjuvant chemotherapy and throughout the study period
- Pregnant or lactating women
- Patients with reproductive potential not implementing adequate contraceptive measures

Contacts and Locations

Locations

Netherlands

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More Information

Responsible Party: Anneriet Dassen, Ms A.E. Dassen, MD, Jeroen Bosch Ziekenhuis

Study ID Numbers:	DoCCS
	Dutch trialregister [Registry ID: NTR2306]
	2007-007273-23 [EudraCT Number]
Health Authority:	The Netherlands: METOPP