Treatment of peritoneal metastases in stomach cancer patients with extensive surgery and heated intraperitoneal chemotherapy

No registrations found.

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

Summary

ID

NL-OMON21196

Source
NTR

Brief title
PERISCOPE

Health condition

Gastric cancer with limited peritoneal dissemination, i.e., positive peritoneal cytology or peritoneal dissemination limited to the upper abdomen with at most one location in the lower abdomen.

Sponsors and support

Primary sponsor: The Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital, Amsterdam, The Netherlands
St. Antonius Hospital, Nieuwegein, The Netherlands
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

Treatment related toxicity (graded according to the NCI Common Toxicity Criteria version 4.0)

Secondary outcome

- postoperative morbidity and mortality

- completion of the study protocol

- pharmacokinetic parameters

- cytoreductive completeness score

- peritoneal cancer index

- patterns of tumour recurrence

- disease free and overall survival

Study description

Background summary

This is a Dutch two center, open label, dose-escalation phase I-II study aimed to evaluate the safety, tolerability and feasibility of HIPEC with oxaliplatin and docetaxel after neoadjuvant systemic chemotherapy with DOC or T-DOC in advanced gastric cancer patients with tumour positive peritoneal cytology (C+) and/or limited peritoneal carcinomatosis (P+). This will be accomplished by enrolling 20-30 patients meeting the inclusion criteria, using a 3+3 design. Safety will be assessed by toxicity graded according to the NCI Common Toxicity Criteria version 4.0.

Study objective

In patients with limited peritoneal dissemination of stomach cancer, following neoadjuvant chemotherapy, cytoreductive surgery combined with hyperthermic intraperitoneal chemotherapy with oxaliplatin and docetaxel is a feasible option.

Study design

Toxicity will be scored following 30 days after cytoreductive surgery and HIPEC, according to the CTC-criteria.

Patterns of tumour recurrence and disease free and overall survival will be measured up to 2 years after cytoreductive surgery and HIPEC.

Intervention

Neoadjuvant treatment

Eligible patients will be scheduled for neoadjuvant systemic chemotherapy involving 3 cycles of docetaxel, oxaliplatin and capecitabine (DOC) - plus trastuzumab in case of a HER2-positive tumour (T-DOC) - at three-weekly intervals.

Surgical procedure

In absence of progressive disease, assessed by CT-scan after the second neoadjuvant chemotherapeutic course, surgery will be planned 3-6 weeks after the last course of chemotherapy. At laparotomy, the presence and extent of peritoneal tumour deposits will be recorded. Any peritoneal fluid is sampled for cytology. When a potentially radical resection of the primary tumour can be achieved, a total or partial gastrectomy with a D2 lymph node dissection is performed. In patients with limited peritoneal carcinomatosis, cytoreductive surgery (CRS) is done with the objective to leave no macroscopic tumour behind.

HIPEC procedure

Intraperitoneal chemoperfusion is performed using an open HIPEC technique. At an intraperitoneal temperature of 41-42 °C, 460 mg/m2 oxaliplatin is added to the perfusate. After 30 minutes, the perfusion fluid is drained from the abdomen. In successive patients a dose-escalation study will be performed with 0-50-75-100-125-150 mg/m2 docetaxel in the peritoneal cavity for 90 minutes.

Contacts

Public
The Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital, Plesmanlaan 121

J.W. Sandick, van
Amsterdam 1066 CX
The Netherlands
Scientific
The Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital, Plesmanlaan 121

J.W. Sandick, van
Amsterdam 1066 CX
The Netherlands

Eligibility criteria

Inclusion criteria

• Biopsy proven adenocarcinoma of the stomach (including tumours at the oesophagogastric junction provided that the bulk of the tumour is located in the stomach for which the intended surgical treatment is a gastric resection, and not a resection of the oesophagus and cardia)

• T3-T4 tumour based upon CT-scan and/or EUS results

• Tumour positive peritoneal cytology and/or peritoneal carcinomatosis limited to the upper abdominal cavity (above the transverse colon) and/or at the most at one location in the lower abdominal cavity (e.g., Douglas' pouch, ovarian metastasis, Sister Mary Joseph nodule) confirmed by diagnostic laparoscopy

• Age ≥ 18 years

• WHO performance status 0-1

• ASA classification I-III

• Adequate bone marrow, hepatic and renal function, i.e., minimal acceptable laboratory values at start of the study inclusion:

a. ANC ≥ 1.5 x 109 /L

b. Platelet count ≥ 100 x 109 /L

c. Serum bilirubin ≤ 1.5 x ULN, and ALAT and ASAT ≤ 2.5 x ULN

d. Creatinine clearance ≥ 50 ml/min (measured or calculated by Cockcroft-Gault formula).

• Wildtype for DPD*2A

• Negative pregnancy test (urine/serum) for female patients of childbearing potential

• Life expectancy ≥ 3 months, allowing adequate follow-up

• Able and willing to undergo blood sampling for pharmacokinetics

• Written informed consent

Exclusion criteria

• Distant metastases (e.g., liver, lung, para-aortic lymph nodes) or small bowel dissemination

• Signs of local irresectability

• Recurrent gastric cancer

• Metachronous peritoneal carcinomatosis

• Prior treatment of gastric cancer with systemic anticancer therapy

• Pregnancy, breast feeding or active pregnancy ambition

• Unreliable contraceptive methods. Patients enrolled in this study must agree to use a reliable contraceptive method throughout the study

• Uncontrolled infectious disease or known Human Immunodeficiency Virus HIV-1 or HIV-2 type

• A known history of hepatitis B or C with active viral replication

• Recent myocardial infarction (< 6 months) or unstable angina

• Uncontrolled diabetes mellitus

• Any medical condition not yet specified above that is considered to possibly, probably or definitely interfere with study procedures, including adequate follow-up and compliance and/or would jeopardize safe treatment

• Known hypersensitivity for any of the applied chemotherapeutic agents and/or their solvents

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-11-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41435
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4105
NTR-old	NTR4250
CCMO	NL42799.031.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41435

Study results

Summary results
N/A