Cytoreductive surgery and Intraperitoneal chemotherapy and for Stomach CAncer: a feasibility study

Published: 15-03-2017
Last updated: 15-04-2024

To assess the safety and feasibility of HIPEC and CS in Western patients with peritoneal metastases of gastric cancer, in terms of morbidity and mortality. Secondary objective is to determine the effect on survival and recurrence.

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

Summary

ID

NL-OMON45753

Source
ToetsingOnline

Brief title
CISCA

Condition

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

Synonym
Gastric peritoneal carcinomatosis, Metastasized Stomach Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Heelkunde, chirurgie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gastric Cancer, HIPEC, Peritoneal carcinomatosis

Outcome measures

Primary outcome

Primary outcome is the safety and feasibility of the intervention, measured by

the percentage of overall surgical complications

Secondary outcome

Secondary outcomes are mortality, postoperative recovery, quality of life,

disease free and overall survival

Study description

Background summary

For patients with peritoneal metastases of gastric origin, there is no consensus on the optimal treatment strategy. Several Asian and Western studies demonstrated hyperthermic intraperitoneal chemotherapy (HIPEC) and cytoreductive surgery (CS) to result in a prolonged survival compared to palliative systemic treatment. Morbidity and mortality rates of HIPEC and CS appear to be acceptable. In the Netherlands, this treatment is not yet introduced, therefor some patients go abroad to receive this treatment.

Study objective

To assess the safety and feasibility of HIPEC and CS in Western patients with peritoneal metastases of gastric cancer, in terms of morbidity and mortality. Secondary objective is to determine the effect on survival and recurrence.

Study design

Mono centre prospective phase II single-arm feasibility study.

Intervention

Hyperthermic Intraperitoneal Chemotherapy and Cytoreductive Surgery.

Study burden and risks

The additional burden for the patient consists of HIPEC and CS.patients will undergo additional staging in order to exclude unresectable disease, and neoadjuvant chemotherapy regimen (3 drugs) instead of a palliative chemotherapy regimen (2 drugs). Postoperative care and outpatient visits are performed according to current protocols on HIPEC and CS for colon cancer and protocols on gastric cancer surgery. The study is associated with a high risk classification. As there is a potential survival benefit, a small chance for curation and possibly a higher quality of life, we consider the additional burden and risks justified. This study is designed as a one group study, which eliminates group relatedness.

Contacts

Public
Selecteer

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Selecteer

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Histologically proven adenocarcinoma of the stomach.
- Surgical resectable carcinoma (T1-4b, N1-3) (table 1)
- Pathological proven peritoneal metastases
- Peritoneal Cancer Index (PCI) *12
- European Clinical Oncology Group (ECOG) performance status 0,1 or 2
- Age * 18
- Written informed consent

Exclusion criteria

- Distant metastases other than peritoneal metastases
- Siewert type I/II gastro-esophageal junction tumor.
- Peritoneal carcinomatosis as a presentation of recurrent disease
- Pregnancy
- Contraindication to cisplatin (e.g. hypersensitivity, HIV infection and inadequate bone marrow, hepatic or renal function)

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):	28-08-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	15-03-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-05-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-08-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-08-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2016-002595-27-NL
CCMO	NL58258.041.16

Study results

Date completed: 23-04-2018

Actual enrolment: 3

Summary results
Trial ended prematurely