Neo-adjuvant chemotherapy, cytoreductive surgery with hypethermic intraperitoneal chemotherapy for peritoneal carcinomatosis of colorectal origin.

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To investigate wether neo-adjuvant chemotherapy followed by cytoreductive syurgery and hyperthermic chemotherapy is feasible and reduces the number of irresectable patients with acceptable morbidity and mortality rates.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peritoneal and retroperitoneal conditions
Study type	Interventional

Summary

ID

NL-OMON38114

Source
ToetsingOnline

Brief title
NACHO-Trial

Condition

- Peritoneal and retroperitoneal conditions
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
peritoneal cancer, peritoneal carcinomatosis

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chemotherapy, Cytoreductive surgery, HIPEC, Peritoneal cacinomatosis

Outcome measures

Primary outcome

Primary objectives

Phase 1 and Phase 2:

• To evaluate the efficacy of neoadjuvant chemotherapy with regard to the

number of patients in whom a complete cytoreductive surgery can be performed.

Secondary outcome

Secondary objectives

1)To evaluate the safety of neo-adjuvant chemotherapy and CRS with HIPEC in

peritoneal carcinomatosis of colorectal origin

2)The response of peritoneal carcinomatosis to chemotherapy according to RECIST

criteria and postoperative pathological examination

3) 30-day or in-hospital mortality following CRS+HIPEC after neo-adjuvant

chemotherapy.

4) Quality of life as measured by the EORTC-QLQ C30 quality of life

questionnaire

5) Morbidity of surgery according to the NCI-CTC v3.0

6) The effect of chemotherapy and CRS with HIPEC on intestinal barrier function

as measured by IFAB levels.

7) The percentage of patients able to complete full treatment

Study description

Background summary

Cytoreductive surgery followed by hyperthermic intra-peritoneal chemotherapy and adjuvant systemic chemotherapy has been found to be a curative procedure in patients with peritoneal carcinomatosis of colorectal origin. Neo-adjuvant chemotherapy is expected to reduce tumorvolume thus facilitating cytoreduction and offers cure to more patients

Study objective

To investigate wether neo-adjuvant chemotherapy followed by cytoreductive syurgery and hyperthermic chemotherapy is feasible and reduces the number of irresectable patients with acceptable morbidity and mortality rates.

Study design

Non randomized observational studyconcisting of 1) phase 1 in which the feasibility of neo-adjuvant chemotherapy followed by cytoreductive surgery an hyperthermic intra*peritoneal chemotherapy is tested in 10 patients with regard to safety. 2) Phase 2 in which 40 more patients are subjected to the new neo-adjuvant chemotherapy scheme after its safety has been determined. In phase 2 we will determine the effect of the new scheme on the percentage of complete cytoreductions.

Intervention

Patients with peritoneal carcinomatosis of colorectal origin will receive 6 cycles of chemotherapy with oxaliplatin and capecitabine(CAPOX-scheme) followed by cytoreductive surgery and hypethermic intra-peritoneal chemotherapy. After 3 cycles a CT-scan of the abdomen will be performed to evaluate the effect of the chemotherapy. If there is a respons or stable disease 3 more cycles of chemotherapy are given. If there is progressive disease under chemotherapy patients will go directly for cytoreductive surgery and hyperthermic intra-peritoneal chemotherapy mif deemed feasible by the treating surgeon. After a complet course of chemotherapy another CT-scan will be performed, when there is no evidence of extra-abdominal or liver metastasis patients will go

for surgery.

Study burden and risks

Patients will receive in hospital chemotherapy through an i.v line, oral chemotherapy will be taken at home during two weeks of every cycle of chemotherapy, regular hospital visits are required, blood samples will be taken at every visit to evaluate the effect of chemotherapy After the chemotherapy a period of 4 weeks to recover will be necessary. After this short period a laparotomy from xiphoid process to the pubic tubercle will be performed to evaluate the resectability. During that procedure, a decision will be made whether to continue with CRS and HIPEC or not. After the operation ICU admission will follow. Average hospital stay is expected to be 14 days postoperatively. Risks involved with this study are the side effects of the chemotherapy. Risks involved with the CRS and HIPEC procedure are primarily related to the nature and extend of the surgical procedure. In case of bowel resection with anastomosis, anastomotic dehiscence might occur. Abscess formation, superficial wound infection, postoperative bleeding, cardiopulmonary events or even death can occur.
These are acceptable risks in view of the fact that chemotherapy in combination with CRS and HIPEC offers improved curation for this patient category.

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

Peritoneal carcinomatosis of colorectal origin diagnosed either by cytologic confirmation of malignant ascitis or by histologic or cytologic confirmation at laparotomy.

Exclusion criteria

Age under 18 years
Previous chemotherapy, exept adjuvant cheomtherapy with an interval between adjuvant chemotheray and start of neo-adjuvant chemotherapy of al least 12 months.
History of other malignancy, except basal cell carcinoma
Advanced liver disease, Child Pugh score > 2
WHO performance status above 2
Unable to give written informed consent
Creatine clearance < 30 ml/min
Liver or extra-abdominal metastasis
Neurotoxicity > grade 2 according to CTC AE 3.0

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	15-04-2013
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Eloxatin
Generic name:	Oxaliplatin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Mitomycin C
Generic name:	Mitomycin C
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Xeloda
Generic name:	Capecitabine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-02-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-01-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 22353
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2010-020787-37-NL
CCMO	NL34659.042.11
OMON	NL-OMON22353