Feasibility study of adjuvant laparoscopic hyperthermic intraperitoneal chemotherapy in patients with colorectal cancer at high risk of peritoneal carcinomatosis

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The aim of this study is to determine the feasibility to perform laparoscopic HIPEC in colorectal cancer patients at high risk of PC in a short stay setting.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON36646

Source
ToetsingOnline

Brief title
Lap. HIPEC study

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
peritoneal cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Colorectal carcinoma, feasibility, HIPEC, laparoscopy

Outcome measures

Primary outcome

Primary endpoint is hospital stay.

Secondary outcome

Secondary endpoints are treatment related morbidity defined as surgical

complications and toxicity related to the intraperitoneal chemotherapy.

Study description

Background summary

The peritoneum is the second most common site of recurrence in patients with colorectal cancer. Cytoreductive surgery and hyperthermic intraperitoneal chemotherapy (CR/HIPEC) in patients with peritoneal carcinomatosis (PC) has been shown to improve survival, but the effectiveness depends highly on the extent of disease. Furthermore, open CR/HIPEC has a substantial complication rate. It seems therefore attractive to treat patients at high risk of PC in an adjuvant setting. Incidences of PC range from 19% in pT4 stage to 75% in patients with isolated ovarian metastases. Because PC is often difficult to detect by imaging modalities, these incidences may be even higher. A laparoscopic HIPEC procedure is potentially an effective oncological procedure with all the advantages of a minimally invasive approach.

Study objective

The aim of this study is to determine the feasibility to perform laparoscopic HIPEC in colorectal cancer patients at high risk of PC in a short stay setting.

Study design

Included patients will undergo laparoscopic HIPEC 4 to 8 weeks after resection of the primary tumour. Subsequently patients will receive adjuvant systemic chemotherapy within 3 to 6 weeks from HIPEC.

Intervention

The laparoscopic HIPEC procedure: open introduction of a 10 mm trocar at the umbilicus, CO2 pneumoperitoneum, three additional trocars of 10 mm, complete dissection of adhesions, peritonectomy or other cytoreductive surgery if indicated, two inflow catheters (right upper quadrant and left paracolonic gutter), one outflow catheter (Douglas pouch), perfusion with a minimum of 2l isotonic dialysis fluid at a flow rate of 1-2l/min and an inflow temperature of 42-43*C, Mitomycin C (17.5 mg/m2 followed by 8.8 mg/m2 every 30 minutes), 90 minutes perfusion time.

Study burden and risks

Patients will have to undergo a laparoscopic HIPEC procedure in short stay setting. Potential risks are woundinfection, gastroparesis or temporary bonemarrow depression, intra-abdominal abcess, and operation associated risks. Benfit is the possible prevention of peritoneal metastasis, however this is not yet confirmed in studies.

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

Patients diagnosed with adenocarcinoma of the colon and proximal rectum and at least one of the following risk factors for PC will be considered for inclusion:
* pT4
* (Resected) local peritoneal nodules in the close proximity of the primary tumour
* Primary tumour presenting with obstruction and/or perforation
* Positivie cytology in peritoneal lavage
* Ovarian metastasis or omental metastasis;Eligibility criteria are:
* age between 18 and 75 years,
* ECOG performance status 0 to 2,
* written informed consent obtained prior to any study specific screening procedures,
* white blood cell count at least 3000/mm3, platelet count at least 100.000/mm3,
* no bleeding diathesis or coagulopathy,
* creatinine normal or creatinine clearance at least 50 ml/min

Exclusion criteria

* liver and/or lung metastases,
* pregnant or lactating women,
* unstable or uncompensated respiratory or cardiac disease,
* serious active infections,
* other concurrent chemotherapy.

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):	01-01-2011
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Mitomycin-C Kyowa
Generic name:	Mitomycin
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	EUCTR2010-023675-26-NL
CCMO	NL34574.018.10