A pilot study evaluating response to induction chemotherapy with oxaliplatin, capecitabine and bevacizumab in patients with extensive peritoneal carcinomatosis of colorectal origin.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON34853

Source
ToetsingOnline

Brief title
induction chemotherapy for PC of CRC

Condition

- Metastases

Synonym
peritoneal carcinomatosis of colorectal cancer, peritoneal metastases/spread of colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: eigen financiering

Intervention

Keyword: Capox/bevacizumab, Colorectal cancer, Neo-adjuvant therapy, Peritoneal carcinomatosis

Outcome measures

Primary outcome

* The primary objective of this study is:

- the study of the response rate and the macroscopic and microscopic response

charactheristics of neo-adjuvant chemotherapy of patients with peritoneal

carcinomatosis (PC) of colorectal origin.

Secondary outcome

* Secundary objectives of this study are:

- assessment of the toxicity of this neo-adjuvant chemotherapy combination.

- assessmet of the drop-out percentage after surgical exploration, the extent

of the PC after this neo-adjuvante therapy still exceeds 5 abdominal regions.

- assessment of the toxicity of complete cytoreductive surgery and HIPEC after

neo-adjuvante treatment in PC of colorectal origin.

Study description

Background summary

* Titel:

*A pilot study evaluating response to induction chemotherapy with oxaliplatin, capecitabine and bevacizumab in patients with extensive peritoneal

carcinomatosis of colorectal origin.*

* Fase:

A phase II pilot study

* Ontwerp:

An open label, non-randomized, uncontrolled, single group assignment, pilot efficacy study.

Study objective

* The primary objective of this study is:
- the study of the response rate and the macroscopic and microscopic response charactheristics of neo-adjuvant chemotherapy of patients with peritoneal carcinomatosis (PC) of colorectal origin.

* Secundary objectives of this study are:
- assessment of the toxicity of this neo-adjuvant chemotherapy combination.
- assessmet of the drop-out percentage after surgical exploration, the extent of the PC after this neo-adjuvante therapy still exceeds 5 abdominal regions.
- assessment of the toxicity of complete cytoreductive surgery and HIPEC after neo-adjuvante treatment in PC of colorectal origin.

Study design

* Design:

An open label, non-randomized, uncontrolled, single group assignment, pilot efficacy study.

* Patients:

About forty-seven (47) patients with initially inoperable peritoneal carcinomatosis of colorectal origin wil undergo neo-adjuvant chemotherapy with oxaliplatin, capecitabine en bevacizumab and subsequently a new investigation will be performed to assess the response rate, possible downstaging under this neo-adjuvant treatment and the macroscopic and microscopic response charactheristics of neo-adjuvant chemotherapy of patients with peritoneal carcinomatosis (PC) of colorectal origin. .

Intervention

1 additional laparoscopy

Study burden and risks

very limited, because only once additional performance of lab, PET/CT and laparoscopy with biopsy, when compared to the normal therapy course of a patient with peritoneal carcinomatosis of colorectal cancer.

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

* Primary tumor: histologically proven adenocarcinoma in appendix, colon or rectum, that can be seen as the primary tumor related to the peritoneale carcinomatosis, and that is still present at inclusion or has been previously resected.
* Intraperitoneal disease: inoperable peritoneal carcinomatosis (i.e. peritoneal carcinomatosis

in more than 5 of 7 abdominal regions) of colorectal origin, histologically proven.
* patients:
- 18 years or older.
- WHO performance status 0 or 1.
- fit to undergo major surgery as well as chemotherapy.
- life expectancy > 4 months without therapy.
- written informed consent, obtained before inclusion in the study.
- normal bone marrow reserve (i.e. leucocytes > 2000/l and thrombocytes > 80,000/l) .
- bilirubine < 2.5 times the normal upper limit.
- ASAT and ALAT < 2.5 times the normal upper limit.
- normal creatinine-level and a negative dipstick-test for protein of < 1 gram protein in a 24-hour urine collection.

Exclusion criteria

- Symptoms of bowel obstruction (in case of symptoms of bowel obstruction bypass-surgery or construction of an ostomy is necessary before inclusion into the study).
- Extra-peritoneal, systemic disease on CT thorax/abdomen. Liver metastases are considered systemic disease, as well as bone metastases.
- Bleeding diathesis of coagulopathy.
- Medical history of CVA or TIA, uncontrolled hypertension, instable angina pectoris, myocardial infarction within 6 months before inclusion, congestif heart failure NYHA class II or higher, arhythmia.
- Instable or uncompensated respiratory disease.
- Neuropathy in the medical history.
- Pregnancy or lactation. Fertile patients who do not use contraceptive drugs.
- Previous or concomitant malignancies in the past 5 years, other then non-melanoma skin cancer or carcinoma in situ.
- Active infection.
- Chemotherapy with oxaliplatin or fluorouracil within 1 year before inclusion, progressive disease under oxaliplatin or fluorouracil at any time before inclusion, any major toxicity in the past, originating from any drugs used in this protocol.
- Short bowel syndrome.
- Surgery within 3 maanden before inclusion, leading to an abdominal sepsis or fistulisation (in case of fistulisation patients must have a stable situation of at least 3 months, without signs of active infection or abscess).
- Previous complete cytoreductive surgery (CCRS) and HIPEC and/or surgery leading to an anatomical situation in which CCRS en HIPEC have become impossible.
- Current therapy with and other investigational agent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-07-2010
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Avastin
Generic name:	Bevacizumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Oxaliplatin
Generic name:	Oxaliplatin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Xeloda
Generic name:	Capecitabine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	02-02-2010
Application type:	First submission
Review commission:	METC NedMec

Approved WMO Date:	03-03-2010
Application type:	First submission
Review commission:	METC NedMec

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	EUCTR2009-017776-24-NL
CCMO	NL30577.031.09