Voorbehandeling met chemotherapie, verwarmde buikspoeling met chemotherapie na chirugische verwijdering van alle tumor bij patienten met buikvlies uizaaiingen van dikke darm of endeldarm kanker.

No registrations found.

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

Summary

ID

NL-OMON22353

Source
Nationaal Trial Register

Brief title
NACHO-trial

Health condition

peritoneal metastasis, colorectal cancer, surgery, cytoreduction,HIPEC
peritoneaal metastasen, chirurgie, neo-adjuvante chemotherapie, cytoreductie, HIPEC

Sponsors and support

Primary sponsor: University Medcal Center Groningen
Source(s) of monetary or material Support: University Medical center Groningen

Intervention

Outcome measures

Primary outcome

Efficacy of neo-adjuvant chemotherapy with respect to the percentage of patients who are resectable after neo-adjuvant chemotherapy.

Secondary outcome

1. The response of peritoneal carcinomatosis to chemotherapy according to RECIST criteria and postoperative pathological examination;

2. Safety of neo-adjuvant chemotherapy and CRS+HIPEC with respect to 30-day or in-hospital mortality;

3. Quality of life as measured by the EORTC-QLQ C30 quality of life questionnaire;

4. Morbidity of surgery according to the NCI-CTC v4.0;

5. The effect of chemotherapy and CRS with HIPEC on intestinal barrier function as measured by IFAB levels;

6. The percentage of patients able to complete full treatment.

Study description

Background summary

Complete surgical removal of tumor (cytoreduction) with hyperthermic intraperitoneal chemotherapy (HIPEC) followed by systemic chemotherapy, has been found to be a potentially curative treatment in peritoneal carcinomatosis of colorectal origin. Treatment schedules not involving cytoreductive surgery and hyperthermic intraperitoneal chemotherapy offer no curation and prolong median survival with 2 years. Surgical treatment without systemic chemotherapy does not prevent lymphogenic and haematogenous spread of the disease as the HIPEC is only directed against intra-abdominal tumor cells. To prevent and/or treat lymphogenic spread systemic treatment is provided. However, after HIPEC treatment many patients are not able to complete their systemic treatment due to the short term postoperative morbidity of the HIPEC. Neo-adjuvant systemic chemotherapy is expected to reduce tumor volume thus facilitating radical cytoreduction and will possibly offer long term curation in more patients. Also by giving the systemic treatment preoperatively, more patients will be able to complete treatment and may as a result have an additional survival benefit.
The feasibility of neo-adjuvant chemotherapy added to cytoreductive surgery with hyperthermic intra-peritoneal chemotherapy will be investigated. Also the efficacy of neo-

adjuvant chemotherapy with regard to the number of patients in whom a complete cytoreductive surgery can be performed, will be studied.

Study objective

Neo-adjuvant chemotherapy facilitates complete cytoreduction without negative effects on safety.Therby offering a possibility of better overall survival.

Study design

Directly postoperative, 30 days postoperative, 3 months, 6 months, 1 year.

Intervention

Neo-adjuvant chemotherapy giving six cycles of oxaliplatin and capecitbine preoperatively followed by cytoreductive surgery and hyperthermic intraperitoneal chemotherapy using mitomycin C.

Contacts

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Eligibility criteria

Inclusion criteria

1. Peritoneal carcinomatosis of colorectal origin diagnosed either at laparotomy or by malignant ascites on CT-scan. When ascites is diagnosed, cytologic confirmation of peritoneal carcinomatosis is sufficient. At laparotomy either histologic or cytologic confirmation of peritoneal carcinomatosis is sufficient;

2. Age of 18 years of older;

3. WHO performance score of 0, 1 or 2;

4. Adequate bone marrow function, defined as platelets > 100 x 109 /l and neutrophils > 1.5 x 109 /l;

5. Adequate renal function, defined as creatinine clearance of > 50 ml/min measured using the Cockroft Gault formula;

6. Informed consent provided.

Exclusion criteria

1. Previous chemotherapy except adjuvant chemotherapy with an interval between the end of adjuvant chemotherapy and the start of neo-adjuvant chemotherapy of at least 12 months;

2. History of other malignancy, exept basal cell carcinoma;

3. Advanced liver disease, defined as bilirubin >34 umol/l and/or PT > 1,7(INR);

4. Liver and/or extra abdominal metastases;

5. Neurotoxicity > grade 1 according CTC AE 4.0.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2013

Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion
Date: 20-03-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38114
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3707
NTR-old	NTR3905
CCMO	NL34659.042.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38114

Study results

Summary results
N/A