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

Gepubliceerd: 20-03-2013 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22353

Bron
Nationaal Trial Register

Verkorte titel
NACHO-trial

Aandoening

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

Ondersteuning

Primaire sponsor: University Medcal Center Groningen
Overige ondersteuning: University Medical center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Hanzeplein 1
P.H.J. Hemmer
Groningen 9700 RB
The Netherlands
+31 (0)50 3612283

Wetenschappelijk

Hanzeplein 1
P.H.J. Hemmer
Groningen 9700 RB
The Netherlands
+31 (0)50 3612283

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-03-2013
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-03-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38114
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A