Relevance of circulating tumor cells in patients undergoing laparoscopic colon resection versus open resection; a randomized trial.

Gepubliceerd: 06-09-2005 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON28393

Bron
Nationaal Trial Register

Verkorte titel
CTC-trial

Aandoening

Colorectal cancer.

Ondersteuning

Primaire sponsor: Academic medical Center, Amsterdam
Overige ondersteuning: Internal research budget

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The amount of circulating tumor material induced by the surgical procedure, measured before, during and after the surgical procedure.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Besides radical surgery, minimal manipulation of the tumor tissue is thought to be essential for the prognosis of patients with colorectal cancer. It is generally thought that lympho-vascular ligation before tumor manipulation reduces intra-operative dissemination of colorectal cancer cells, however evidence is scarce.

Aim:

To eveluate the influence of laparoscopic surgery on the amount of circulating tumor cells and cancer biology.

Patients included in this study will be a subset of the contribution to the LAFA-trial. First, a pilot experiment will be conducted for which we will include 5 (lap) versus 5 patients (open) to test the experimental set up. In total this study is powered to include 30 patients (15 versus 15).
Blood will be collected by venapuncture and by inserting a catheter in a large draining mesenterical vene according standard conditions.

Doel van het onderzoek

We hypothesize that free circulating tumor cells can be detected during surgery in patients with colorectal cancer. Since minimal invasive surgery causes less trauma and tumor manipulations we hypothesise that the amount of free circulating tumor cells is less compared to the level detected during open surgery in comparable patient groups. Minimal invasive surgery causes less severe impairment of the immune system compared to open surgery. Since the surgical trauma might enhance tumor shedding and compromises immune function, the minimally invasive surgery for colorectal cancer might both lower the risk of tumor shedding and result in less compromised immune down regulation resulting in better protection against tumor shedding.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Laparoscopic surgery compared to open surgery for colorectal cancer.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age between 40 and 80 years;

2. colorectal cancer including colon and rectosigmoid cancers;

3. informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Prior midline laparotomy;

2. ASA III/IV;

3. Laparoscopic surgeon not available;

4. Prior upper and/or lower midline laparotomy;

5. Emergency colectomy;

6. Contraindications for epidural (coagulation disorders).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2005
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL239
NTR-old	NTR277
Ander register	: N/A
ISRCTN	ISRCTN28212149

Resultaten

Samenvatting resultaten
N/A