A pilot study to assess the safety and feasibility of fluorescent sentinel lymph node identification in colon carcinoma using Indocyanine green.

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The sentinel lymph node procedure for cT1-T2 colon carinoma is a safe and feasible procedure.

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

Samenvatting

ID

NL-OMON24349

Bron
Nationaal Trial Register

Verkorte titel
FLUOR-SLN-ICG

Aandoening

cT1-T2 colon carcinoma

Ondersteuning

Primaire sponsor: Meander Medical Centre, Department of Surgery
Overige ondersteuning: 't Stichts Genootschap, EAES

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Identification rate of SLN with ICG: Number of patients with one or more SLNs identified / total number of procedures (n, %).
2. Adverse events related towards ICG: Number of adverse events related towards ICG / total number of procedures (n, %).

Toelichting onderzoek

Achtergrond van het onderzoek

The current gold standard for the treatment of colon carcinoma consists of the surgical enbloc resection of the colonic segment including the adjacent mesocolon containing the draining lymph nodes. Analysis of these lymph nodes is important, since lymph node status is one of the most important prognostic factors determining the use of adjuvant chemotherapy. Although patients with tumour stage I and" do not have lymph node metastases, 15-20% develop recurrent disease. Several studies suggest that ultrastaging techniques such as immunohistochemistry (IHC) or reverse transcriptase polymerase chain reaction (RT-PCR) using multilevel slicing results in upstaging of 14-18% of patients, due to newly found (micro)metastasis. Furthermore, several studies indicate that these micrometastases are correlated with a significantly poorer prognosis, subsequently suggesting that this subgroup of patients might benefit of adjuvant chemotherapy. Therefore, the most recent Dutch guidelines advice the use of adjuvant chemotherapy in this "upstaged" group, although evidence is still lacking.

However, ultrastaging techniques are labour-intensive and costly, and therefore not suitable for analyses of all lymph nodes that have been collected during segmental colectomy. Sentinel lymph node (SLN) identification in colon carcinoma has been proposed to overcome this problem by identifying the first order draining lymph node(s) of the tumour, which have the highest chance of containing metastatic tumour cells. Several studies aimed at SLN identification in colon carcinoma have been published, however, early studies using radioguided or blue-dye guided SLN identification, showed relatively high rates of false negatives with consequent low sensitivity rates. Since mesocolon is rather fatty tissue, visualization of conventional dyes is difficult. Indocyanine green (ICG), which can be visualized using near infrared (NIR), has been put forward since it is known to penetrate relatively deep into living tissue.

Nevertheless, results of SLN identification using ICG remain unsatisfying with high false negative rates and low sensitivity. Most likely this is due to the fact that these studies also included large cT3-cT 4 tumours and patients with massive lymph node involvement. Which are factors known to interfere with lymph drainage patterns. Furthermore, subserosal injections were frequently used, while it is suggested that submucosal injections might result in better sensitivity of the procedure. Therefore this prospective study aims to assess the safety and feasibility of lymph node identification using ICG in patients with cT1-cT2 tumours, without gross lymph node involvement, using peritumoral submucosal injections.

Doel van het onderzoek

The sentinel lymph node procedure for cT1-T2 colon carinoma is a safe and feasible procedure.

Onderzoeksopzet

Outcome 1, 3, 4, 5, 8 are measured after pathological ultrastaging.
Outcome 2 is measured from start of ICG injection (intervention) until 30 days after surgery.
Outcome 7 is determined during surgery: presence of aberrant lymph node yes/no. And the presence of metastases in aberrant lymph nodes is determined after pathological ultrastaging.

Onderzoeksproduct en/of interventie

Patients will then undergo robot-assisted surgery, they will be prepped, draped and placed under general anesthesia. Robot-assisted access will be obtained in the traditional fashion and abdominal exploration shall be performed to rule out intra-abdominal metastasis. The involved segment is mobilized carefully without disruption of the lymphatic channels and blood vessels. During segmental robot-assisted colectomy a colonoscopy will be performed by the gastroenterologist on the operation room. A bowel clamp will be placed over the distal ileum, and C02 will be used by the gastroenterologist to prevent massive intestinal distension. The colonoscopy will be done while intra-abdominal access is achieved by the surgeon with the Da Vinci. The gastroenterologist will administer two to four blebs of IGG peritumoral and submucosal. The SLN will be visualized using NIR light with the Firefly modus of the Da Vinci Xi (Intuitive Surgical Inc., Sunnyvale, USA), a suture will be placed to mark the observed SLN(s). In case there is an aberrant sentinel node (outside the planned resection margins) this sentinel node will be harvested. After mobilization is completed the involved segment of the colon and the regional lymph nodes will be resected in a conventional manner. After extraction of the specimen (segmental colectomy including regional lymph nodes), ex-vivo examination of the specimen using the Firefly camera will be done to visualize the location of the SLN(s). The entire specimen and all biopsies will be submitted for pathologic examination. Postoperative management for patients will be according to standard of care.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Oral and written informed consent (IC);
- Aged 18 years and older;
- Pathologically confirmed and/or suspected T1-T2 colon carcinoma without (suspected) lymph node metastases.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Distant metastasis;
- cT3- T 4 disease based on pre-operative assessment;
- Metastatic or T 4 disease discovered during intraoperative staging;
- A tumour too large to pass endoscopically;
- Pregnancy, lactation or a planned pregnancy during the course of the study.
- Known allergy to any of the compound used for SLN identification (ICG, iodine or sodium iodide);
- Suspected or proven lymph node metastasis;
- Previous colon surgery;
- Contra-indication for robotic surgery;
- Ink marking close to the tumour;
- Severe kidney- or liver failure;
- Hyperthyroidism or an autonomously functioning thyroid adenoma.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-09-2020
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-09-2020
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	NL8901
Ander register	MEC-U : R19.056

Resultaten