Intra-operative fluorescent imaging of the tumor border and sentinel lymph nodes in rectal and sigmoid cancer

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Intraoperative endoscopic marking of the tumor can assist in detection of tumor border and possibly decrease tumor involvement of the resection margin. Moreover, intraoperative endoscopic marking of the tumor can result in detection of the SLNs.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27686

Bron
NTR

Verkorte titel
GREEN LIGHT

Aandoening

Bowel cancer

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)
Overige ondersteuning: Leiden University Medical Center (LUMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Percentage of patients in whom SLN identification was possible using NIR fluorescence imaging
2. Percentage of patients in whom intraopertive detection of the tumor border was possible by NIR fluorescence imaging

Toelichting onderzoek

Achtergrond van het onderzoek

The SLN procedure has been proposed to improve nodal staging in colorectal cancer patients. Moreover, the resection margins is prognostic in survival after rectal cancer surgery. Current treatment includes neoadjuvant chemoradiation therapy, which often result in regression of the tumor. This makes intraoperative tumor detection more difficult. Intraoperative endoscopic marking of the tumor can assist in detection of tumor border and possibly decrease tumor involvement of the resection margin. Moreover, intraoperative endoscopic marking of the tumor can result in detection of the SLNs.

Doel van het onderzoek

Intraoperative endoscopic marking of the tumor can assist in detection of tumor border and possibly decrease tumor involvement of the resection margin. Moreover, intraoperative endoscopic marking of the tumor can result in detection of the SLNs.

Onderzoeksopzet

The primary and secondary outcomes will be assessed during surgery and pathological assessment.

Onderzoeksproduct en/of interventie

After general anesthesia, prior to incision, ICG;NanoColl will be injected endoscopically around the tumor. During surgery, fluorescence imaging will be performed to visualize tumor border and lymph nodes.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Colorectal cancer patients scheduled for laparoscopic low anterior resection.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History of allergy to iodine, shellfish, indocyanine green or nanocolloid;

2. Pregnancy;

3. Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	28-10-2013
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL4541
NTR-old	NTR4682
Ander register	: P09.001 METC LUMC

Resultaten

Samenvatting resultaten
NA