SGM-101 in Locally Advanced and Recurrent Rectal Cancer

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The investigators hypothesize that the use of FGOS will increase the amount of R0 resections from 75 to 90% in locally advanced rectal cancer and from 50 to 70% in recurrent rectal cancer.

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

Samenvatting

ID

NL-OMON28772

Bron
Nationaal Trial Register

Verkorte titel
SGM-LARRC

Aandoening

Locally advanced and recurrent rectal cancer

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: SurgiMab
Quest Medical Imaging
KWF

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- The primary objective is based on the clinical benefit of FGOS combined with SGM-101 as the intraoperative imaging agent. The corresponding endpoint is the rate of patients with R0 resections.

Toelichting onderzoek

Achtergrond van het onderzoek

This is a national phase III, multicenter, open label clinical trial on the performance of SGM-101, a fluorochrome-labeled anti-carcino-embryonic antigen (CEA) monoclonal antibody, for the delineation of locally advanced and recurrent rectal cancer. Patients will be followed for a total duration of two years postoperatively.

Doel van het onderzoek

The investigators hypothesize that the use of FGOS will increase the amount of R0 resections from 75 to 90% in locally advanced rectal cancer and from 50 to 70% in recurrent rectal cancer.

Onderzoeksopzet

2 years post-treatment

Onderzoeksproduct en/of interventie

SGM-101, a fluorochrome-labeled anti-carcino-embryonic antigen (CEA) monoclonal antibody, for the delineation of locally advanced and recurrent rectal cancer

Contactpersonen

Publiek

LUMC
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Wetenschappelijk

LUMC
Ruben Meijer

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Signed informed consent prior to any study-mandated procedure;
2. Patients aged over 18 years old;
3. All women of child bearing potential and all males must practice effective contraception during the study and be willing and able to continue contraception for at least 90 days after their last dose of study treatment.
4. Patients should be scheduled and eligible for surgery because of a clinical diagnosis of T3 with a threatened CRM or T4 rectal cancer (locally advanced) or recurrent rectal cancer. (UICC. TNM classification of diseases for oncology. 3rd ed. Geneva: World Health Organization; 2000)
5. Patients should be capable and willing to give informed consent before study specific procedures.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Other malignancies, either currently or in the past five years, except adequately treated in situ carcinoma of the cervix and basal or squamous cell skin carcinoma.
2. Patients with a history of, or recently diagnosed with, peritoneal or distant metastasis (even those diagnosed during surgery)
3. Patient with a history of a clinically significant allergy.
4. Patients pregnant or breastfeeding lack of effective contraception in male or female patients with reproductive potential;
5. Laboratory abnormalities defined as:
a. Aspartate AminoTransferase, Alanine AminoTransferase, Gamma Glutamyl Transferase) or Alkaline Phosphatase levels above 5 times the or;
b. Total bilirubin above 2 times the ULN or;
c. Serum creatinine above 1.5 times the ULN or;
d. Platelet count below 100 x 109/L or;
e. Hemoglobin below 4 mmol/L (females) or below 5 mmol/l (males);
f. Known positive test for human immunodeficiency virus (HIV), hepatitis B surface antigen (HBsAG) or hepatitis C virus (HCV) antibody or patients with untreated serious infections;
6. Any condition that the investigator considers to be potentially jeopardizing the patients' well-being or the study objectives.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2019
Aantal proefpersonen:	203
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 56317
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7653
CCMO	NL69838.056.19
OMON	NL-OMON56317

Resultaten