Study on the detection of cancer during surgery for rectal cancer or pancreatic cancer with the fluorescent agent "SGM-101 '

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

Samenvatting

ID

NL-OMON21037

Bron
NTR

Verkorte titel
n/a

Aandoening

rectal cancer
pancreatic cancer

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC) and Centre for Human Drug Research (CHDR), Leiden, the Netherlands
Overige ondersteuning: Surgimab, Montpellier, France

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Safety and tolerability (primary endpoint)
Tolerability/safety will be assessed using routine clinical measures such treatment-emergent adverse events,
blood pressure, heart rate, temperature, peripheral oxygen saturation, respiratory rate, skin examination, and
routine laboratory assessments. DLT is defined as grade ≥ 3 NCI-CTCAE V4.03 toxicity related to SGM-101 treatment between the day of injection and 10 days after surgery. The MTD is defined as the dose at which at least two out of two-to-six patients experience one DLT in the observation sequence defined as the interval between infusion of SGM-101 and 10 days after the surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

Surgery is the most important therapy for patients with cancer of the rectum or pancreas. Complete resection,
which is a crucial factor in the prognosis of a patient, is challenging as surgeons have to rely on visual appearance and palpation to discriminate between tumor and normal tissue. Consequently, incomplete resection of malignant tissue or unnecessary removal of healthy tissue may occur. This problem may become bigger as ‘open’ surgery is increasingly replaced by ‘closed’ (laparoscopic) surgery. It is therefore that realtime intra-operative imaging techniques are developed. Particularly the use of tumor-specific markers coupled to fluorescent imaging moieties show great promise to improve intraoperative staging and allow more radical cytoreductive surgery. Carcinoembryonic antigen (CEA) is a tumor-specific marker that is highly expressed in a number of tumors of
epithelial origin (such as colorectal carcinoma and pancreas carcinoma) while it is minimally expressed in
normal adult tissues. Anti-CEA monoclonal antibodies have been used in more than 100 clinical studies
without any toxicity concerns. In addition, it has been shown that it is possible to link an anti-CEA monoclonal
antibody to a near-infrared (NIR) emitting fluorophore. The compound that will be studied in this research
project is SGM-101, a CEA-specific chimeric antibody conjugated with a NIR emitting moiety developed by
SurgiMab (Montpellier, France). The hypothesis is that, following preoperative iv administration of SGM-101 in
patients with carcinoma of the rectum or pancreas, SGM-101 will bind to CEA expressing cancer cells and

these cells can then be visualized with a NIR fluorescence imaging system, thereby increasing the chance of
radical resection.

As the experience with SGM-101 in humans is limited, an escalating dose design will be used which allows assessment of safety and will yield data on the most appropriate dose to be used in subsequent clinical studies.

Doel van het onderzoek

The hypothesis is that, following preoperative iv administration of SGM-101 in patients with carcinoma of the rectum or pancreas, SGM-101 will bind to CEA expressing cancer cells and these cells can then be visualized with a near-infrared fluorescence imaging system, thereby increasing the chance of radical resection.

Onderzoeksopzet

For each patient the study period will be approximately 15 weeks. Maximally 4 (±1) weeks before the scheduled surgery eligibility of the patient will be assessed. Ar least 24hrs before surgery the patient will be admitted to CHDR for 12 hours for baseline measurements, study drug administration and assessments. The patient will be admitted to LUMC for surgery and other protocol-related assessments. The duration of admission to LUMC is
based on the clinical post-operative course of the individual patient. Follow-up visits are planned on the day of discharge from the LUMC and on the day of the first outpatient post-operative follow-up visit.

Onderzoeksproduct en/of interventie

Intravenous administration of 5, 7.5, 10, 12.5 or 15 mg SGM-101

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients aged over 18 years old;

2. Patient should be scheduled and eligible for surgery because of a clinical diagnosis of cancer of the
rectum or cancer of the pancreas;

3. Circulating plasma CEA ≥ the upper limit of normal range (eg ≥ 3.0 ng / ml);

4. Patients should be capable and willing to give informed consent before study specific procedures.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Anticancer therapy (e.g. chemotherapy, radiotherapy(except routine pre-operative radiotherapy for
rectal cancer), targeted therapy, concomitant systemic immune therapy, or any experimental therapy)
within 4 weeks before inclusion;

2. History of a clinically significant allergy;

3. Circulating plasma concentration CEA ≥ 300 ng / ml;

4. Other malignancies either currently active or diagnosed in the last 5 years, except adequately treated
in situ carcinoma of the cervix and basal or squamous cell skin carcinoma;

5. Patients pregnant or breastfeeding (pregnancy should be ruled out by an assay of βhCG plasma
within two weeks prior to administration of the conjugate), lack of effective contraception in male or

female patients with reproductive potential;

6. Laboratory abnormalities defined as:

Rectal cancer patients only:

 Aspartate AminoTransferase, Alanine AminoTransferase, Gamma Glutamyl Transferase) or Alkaline Phosphatase levels above 5 times the or;

 Total bilirubin above 2 times the ULN or;

Both pancreatic and rectal cancer patients:

 Serum creatinine above 1.5 times the ULN or;

 Absolute neutrophils counts below 1.5 x 109/L or;

 Platelet count below 100 x 109/L or;

 Hemoglobin below 4 mmol/L (females) or below 5 mmol/l (males);

7. 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;

8. Any condition that the investigator considers to be potentially jeopardizing the patients well-being or
the study objectives.

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:	23-01-2015
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47359
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5551
NTR-old	NTR5673
CCMO	NL54512.056.15
OMON	NL-OMON47359

Resultaten