A phase I study assessing the safety and performance of VB5-845D-800CW, an fluorescent agent, for the intraoperative detection of gastrointestinal cancer

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To determine the safety and tolerability and to assess the PK and performance of VB5-845D-800CW in healthy volunteers and patients

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

Samenvatting

ID

NL-OMON27469

Bron
NTR

Verkorte titel
Study for intra-operative imaging of gastrointestinal cancer using VB5-845D-800CW

Aandoening

Colorectal and Gastrointestinal cancer

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Healthy volunteers
• To determine safety and tolerability of a single dose of VB5-845D-800CW in healthy volunteers.
Patients
• To assess safety of different doses of a single i.v. injection of VB5-845D-800CW.

Toelichting onderzoek

Achtergrond van het onderzoek

According to international guidelines, surgery is the primary care for achieving curation in many cancer types. During surgery, the surgeon mainly has to rely on pre-operative imaging modalities to predict the localization of the tumor and the extension of (tumor)tissue that has to be resected. Due to the new era of neo-adjuvant therapies, such as chemotherapy and radiotherapy, downstaging of tumors has become more common before surgery1,2. Consequently, intra-operative detection of tumors and tumor margins has become even more challenging for the surgeon since differentiation between vital tumor cells and chemotherapy induced necrosis or fibrosis can be challenging. Near-infrared fluorescence imaging is a technique that has gained a lot of attention over the last decade because of its role in intra-operative tumor tissue imaging3. This real-time imaging modality could provide clear tumor identification and demarcation and could become a useful tool to reduce positive resection margins. Subsequently, this technique can reduce rates of re-interventions and therefore improve patient outcome.

Patients will be recruited in the Netherlands

Doel van het onderzoek

To determine the safety and tolerability and to assess the PK and performance of VB5-845D-800CW in healthy volunteers and patients

Onderzoeksopzet

• Day 0 – Day 2

Onderzoeksproduct en/of interventie

• VB5-845D-800CW

• Placebo

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Part A (healthy volunteers)

A maximum of sixteen (16) healthy volunteers will take part in this study.

Inclusion criteria

- The subject is 18-65 years old at screening.

- The subject is able and willing to comply with study procedures, and signed and dated informed consent is obtained before any study-related procedure is performed.

- Female subjects need to be surgically sterile, post-menopausal or pre-menopausal with a negative urine pregnancy test at screening and just before administration of VB5-845D-800CW. Pre-menopausal female subjects have to agree to use an effective method of contraception for 90 days after administration. Male subjects have to agree to use an effective method of contraception for 90 days after administration.

- The subject has a normal or clinically acceptable medical history, physical examination, and vital signs findings at screening.

- The subject’s screening ECG and clinical laboratory test results are within normal limits, or if any are outside of normal limits they are considered to be clinically insignificant.

- The subject has negative screening test results for hepatitis B, hepatitis C, and human immunodeficiency virus.

- The subject has negative test results for drug and alcohol screening.

- Absence 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.

• Part B (patients)

The study will be performed in maximum 18 patients. At each dose level 6 patients will be studied, 3 patients for each indication. An additional 3 patients will be included for each indication in the cohort with the most optimum dose level.

Inclusion criteria

- Patients > 18 years;

- Patients capable and willing to give informed consent before study specific procedures;

- Patients with suspected esophageal/gastric- or rectosigmoid cancer, planned for an open or laparoscopic esophageal/gastric resection or sigmoid/low anterior resection respectively;

- Normal and clinically acceptable medical history, medical physical examination and vital signs at screening;

- The subject’s clinical laboratory tests are within normal limits, or if any are outside of normal limits they are considered to be clinically insignificant;

- Absence of any physiological, 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Part A (healthy volunteers)

A maximum of sixteen (16) healthy volunteers will take part in this study.

Exclusion criteria

- Female subjects that are lactating or pregnant.

- Unacceptable known diagnoses or diseases at baseline, e.g., known cardiovascular or pulmonary disease, renal or liver dysfunction, ECG or laboratory abnormalities, etc.

- Use of prescription drugs, with the exception of contraceptive drugs.

- Participation in a clinical trial within 90 days of screening or more than 4 times in the previous year.

- History of significant allergies or anaphylactic reactions.

• Part B (patients)

The study will be performed in maximum 18 patients. At each dose level 6 patients will be studied, 3 patients for each indication. An additional 3 patients will be included for each indication in the cohort with the most optimum dose level.

Exclusion criteria

Patients will be excluded if any of the criteria below apply:

- History of a clinically significant allergy or anaphylactic reactions;

- Patients pregnant or breastfeeding;

- 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:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	34
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-10-2018
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	NL7363
NTR-old	NTR7570
Ander register	: CHDR1737

Resultaten

Samenvatting resultaten
N.A.