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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27469

Source
Nationaal Trial Register

Brief title
Study for intra-operative imaging of gastrointestinal cancer using VB5-845D-800CW

Health condition

Colorectal and Gastrointestinal cancer

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Healthy volunteers

• To determine the pharmacokinetics of VB5-845D-800CW by measuring fluorescence in blood and urine samples and evaluating the relationship of fluorescence in superficial tissue (skin) and mucous membranes (lips).

• To determine the time of injection (and window) for part B

Patients

• To define the optimal dose and injection time of VB5-845D-800CW for intraoperative imaging of esophageal/gastric- and rectosigmoid cancer using near-infrared fluorescence, defined as the dose with the largest difference in mean fluorescence intensity (MFI) between tumor and surrounding tissue

• To assess the performance of VB5-845D-800CW in the intraoperative detection of esophageal/gastric- or rectosigmoid cancer by:

o Tumor-to-background ratio (TBR)

o Concordance between fluorescent signal and tumor status and EpCAM expression of resected tissue

Study description

Background summary

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

Study objective

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

Study design

• Day 0 – Day 2

Intervention

• VB5-845D-800CW

• Placebo

Contacts

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Eligibility criteria

Inclusion criteria

• 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.

Exclusion criteria

• 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2018
Enrollment:	34
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7363
NTR-old	NTR7570
Other	: CHDR1737

Study results

Summary results
N.A.