SGM-101 in Locally Advanced and Recurrent Rectal Cancer

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28772

Source
Nationaal Trial Register

Brief title
SGM-LARRC

Health condition

Locally advanced and recurrent rectal cancer

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: SurgiMab
Quest Medical Imaging
KWF

Intervention

Outcome measures

Primary outcome

- 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.

Secondary outcome

- To determine the effect of FGOS combined with SGM-101 on intra-operative decision making. The corresponding endpoint is the clinical benefit at the patient level; a “positive” change in surgical plan or post-surgical management. Moreover, standard of care surgery will be compared to FGOS and assessing if the latter allowed to remove any additional histopathologically confirmed malignant lesions and/or to resect less non-malignant tissue.
- To determine the performance of SGM-101 in the intra-operative detection of rectal cancer. The corresponding endpoint will be the tumor-to-background ratio. In addition, the concordance between fluorescent signal and histopathologic results will be defined.
- To compare intra-operative fluorescence imaging with SGM-101 and histopathology. The corresponding endpoints will be the rate of false negatives, false positives, true negatives and true positives.
- To determine the changes in surgical planning due to FGOS combined with SGM-101 on mortality and postoperative complications caused by the surgical procedure. The corresponding endpoints are 30-day mortality and 30-day complication rates in order to substantiate the benefit/risk assessment of the use of SGM-101.
- To determine the effect of FGOS combined with SGM-101 on overall and disease-free survival, and to determine the effect on local recurrence rates. The corresponding endpoints will be the 2-year overall survival, 2-year disease-free survival and 2-year local recurrence free survival.

Study description

Background summary

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.

Study objective

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.

Study design

2 years post-treatment

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2019
Enrollment:	203
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 56317
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results