Intraoperative near-infrared fluorescence imaging of colorectal carcinoma with cRGD-ZW800-1 and dedicated imaging systems: A Phase II study

No registrations found.

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

Summary

ID

NL-OMON22876

Source
Nationaal Trial Register

Brief title
cRGD-ZW800-1

Health condition

Colorectal carcinoma

Sponsors and support

Primary sponsor: Leiden University Medical Center, Leiden, the Netherlands
Source(s) of monetary or material Support: KWF

Intervention

Outcome measures

Primary outcome

To assess the feasibility of cRGD-ZW800-1 to visualize tumors in real-time using dedicated

NIR fluorescence imaging systems

Secondary outcome

To define the optimal dose of cRGD-ZW800-1 for intraoperative near-infrared fluorescence imaging of tumors.

Study description

Background summary

Surgery remains the primary treatment for colorectal cancer where complete removal of all malignant tissue is the cornerstone of curative intended oncologic surgery. However, discriminating between malignant and benign tissue can be challenging, especially after neoadjuvant treatment. Near-infrared fluorescence imaging with cRGD-ZW800-1 can provide accurate and real-time visualization of tumors during surgery.

Study objective

Real-time visualization of colorectal carcinoma during surgery with fluorescence

Study design

-

Intervention

cRGD-ZW800-1 injection prior to surgery

Contacts

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Eligibility criteria

Inclusion criteria

1) Patients > 18 years old;
2) Patients scheduled and eligible for resection because of colorectal carcinoma;
3) Patients should be capable and willing to give informed consent before study specific procedures;
4) 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;
5) The patient has a normal or clinically acceptable medical history, physical examination, and vital signs findings at screening;
6) 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.

Exclusion criteria

Patients will be excluded if any of the criteria below apply:
1) History of a clinically significant allergy or anaphylactic reactions;
2) Patients pregnant or breastfeeding, lack of effective contraception in male or female patients with reproductive potential;
3) 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:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-09-2018
Enrollment:	12
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	10-05-2019
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	NL7724
Other	METC LUMC : P17.242

Study results