Optical Imaging for lymph node metastatic guidance in minimally Invasive esophagectomy

No registrations found.

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

Summary

ID

NL-OMON25371

Source
NTR

Brief title
IMAGINE study

Health condition

Esophageal cancer

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: UMCG/ Radboudumc

Intervention

Outcome measures

Primary outcome

·Intra-operative accumulation of Bevacizumab-800CW in VEGF-A overexpressing tissue as detected with intraoperative fluorescence imaging

Secondary outcome

· Adverse events (AE), serious adverse events (SAE), and suspected unexpected serious and adverse reactions (SUSARs).
· Fluorescence signal in malignant and non-malignant tissue: signal-to-background ratio and tumor-to-normal ratio as measured by ex-vivo fluorescence measurements
· Correlation between localization of the fluorescently-labeled antibody and expression of the biomarker in tumor and healthy tissue.
· The effect of neoadjuvant chemoradiotherapy (nCRT) on the fluorescence signal; difference in results between patients treated with nCRT or without nCRT
· The optimal dose for further research, defined as the lowest dose at which a fluorescent signal is still detectable in vivo.

Study description

Background summary

There is a need for better visualization of resection margins and detection of small tumor deposits during surgery for esophageal cancer. Optical molecular imaging of esophageal adenocarcinoma (EAC) associated biomarkers is a promising technique to accommodate this need. The biomarker Vascular Endothelial Growth Factor (VEGF-A) is overexpressed in esophageal adenocarcinoma and its lymph node metastases and has proven to be a suitable target for molecular imaging

Study objective

We hypothesize that the VEGF-targeting antibody Bevacizumab labeled with the fluorophore IRDye800CW (Bevacizumab-800CW) accumulates in VEGF-A expressing cancer, enabling esophageal cancer visualization using a NIR minimally invasive intra-operative camera system. In this pilot intervention study we will determine the optimal dosage of Bevacizumab-800CW (4.5, 10 or 25 mg) to detect esophageal cancer tissue intra-operatively.

Study design

-

Intervention

Targeted fluorescence imaging

Contacts

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Eligibility criteria

Inclusion criteria

· Patients scheduled for minimally invasive esophagectomy
· Suspected lymph node metastases based on EUS, PET or CT
· WHO performance score 0-2
· Aged 18 years or older
· Providing informed consent

Exclusion criteria

· Known pregnancy or breastfeeding
· Known allergic reaction to Bevacizumab or other monoclonal antibody therapies
· Other invasive malignancy
· Inadequately controlled hypertension

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2017
Enrollment:	28
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-03-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50437
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5969
NTR-old	NTR6343

Register	ID
CCMO	NL61189.042.18
OMON	NL-OMON50437

Study results