OptIcal MetAstatic Guidance in mInimally iNvasive Esophagectomy: a multicentre phase I/II diagnostic study

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON50437

Source
ToetsingOnline

Brief title
Imagine study

Condition

- Gastrointestinal therapeutic procedures

Synonym
esophageal cancer, esophageal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: esophageal carcinoma, esophagectomy, fluorescence, lymph node metastases

Outcome measures

Primary outcome

• Intra-operative accumulation of bevacizumab-800CW in VEGF-A overexpressed tissue as detected with fluorescence imaging and histological analyses

• Adverse events (AE), serious adverse events (SAE), and suspected unexpected serious and adverse reactions (SUSARs).

Secondary outcome

• Number of patients in whom lymph node metastases can be visualized by fluorescence imaging during surgery

• Fluorescence signal in malignant and non-malignant tissue: single-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

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 valid target for molecular imaging. We hypothesize that Bevacizumab-800 CW 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-800 CW (4.5, 10 or 25 mg) to detect esophageal cancer tissue intra-operatively.

Study objective

The aim of this present feasibility study is to determine the safety and preliminary accuracy by which we can intra-operatively detect residual disease in esophageal tumor and lymph nodes. This study is set up as a prospective multi-centre dose finding trial, using a single arm

Study design

Non-randomised multicenter feasibility and dose escalation trial.

Study burden and risks

Time investment for study participants
Esophageal cancer patients who are scheduled for surgery with curative intent either at Radboudumc or UMCG are asked to participate in this trial. One study specific visit for administration of the tracer is necessary. In addition to the surgical procedure the study related procedures are expected to take up to 30 minutes extra as compared to regular practice.

Risks for study participants
In this study, risks to study participants are mainly related to the administration of the tracer. Safety data related to the administration of the tracer will be collected and evaluated. Based on previous research (breast cancer NCT01508572; adenomatous poliposis coli NCT02113202; rectal cancer NCT01972373; and in esophageal cancer dysplasia NCT02129933) no adverse events are expected following administration of bevacizumab-800 CW. The normal treatment, esophagectomy, is an extensive procedure with a substantial risk of complications[1]. Interference with standard clinical care is not expected since the surgeons will follow their normal standard of care during surgery. The intra-operative fluorescence imaging is derived during a minimal invasive procedure and will increase the surgical time by approximately 30 minutes. It is up to the surgeon to reduce the imaging time during surgery if the study procedures takes longer than expected. If the extra time of the surgery interferes with the safety of the patient the research protocol is terminated.

Benefits for study participants
The addition of intra-operative fluorescence imaging does not have direct benefits for the participating patients. If fluorescent signals are detected during surgery in parts that are not enclosed in the regular surgical specimen, a maximum of 2 biopsies per fluorescent area may be taken to confirm during

ex-vivo analyses if the fluorescent signals represent cancer tissue.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age >= 18 years.
* Patients with clinical suspicion of esophageal adenocarcinoma who are scheduled to undergo surgical intervention with curative intent
* WHO performance score 0-2.
* Signed written informed consent

Exclusion criteria

• Known hypertension to bevacizumab or other monoclonal antibody therapies
• Other invasive malignancy
• Inadequately controlled hypertension
• Squamous cell carcinoma

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	28
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-05-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25371
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2017-002790-19-NL
CCMO	NL61189.042.18
OMON	NL-OMON25371

Study results

Summary results
Trial never started