Detection of upper GI tumour depth and demarcation by quantified fluorescence molecular endoscopy using systemic administration of ICG during endoscopic submucosal dissection

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The primary objective is to evaluate the feasibility of ICG-enhanced near-infrared qFME to determine tumour demarcation and tumour depth in upper GI tumours (e.g. HGD or superficial oesophageal and/or gastric adenocarcinoma (T1)) during ESD.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON57439

Source
ToetsingOnline

Brief title
BRIGHT

Condition

- Gastrointestinal neoplasms benign

Synonym
esophageal cancer, gastric cancer, upper gastrointestinal tumours

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Endoscopic submucosal dissection, Fluorescence, indocyanine green (ICG), tumour demarcation

Outcome measures

Primary outcome

The primary endpoint is to evaluate the feasibility of ICG-enhanced

near-infrared qFME to determine tumour demarcation and tumour depth in upper GI

tumours (e.g. HGD or superficial oesophageal and/or gastric adenocarcinoma

(T1)) compared to healthy tissue during ESD .

Secondary outcome

Secondary endpoints include: to histopathologically determine R0 resection rate

to, quantify and evaluate in vivo NIR fluorescent signals of indocyanine green

(ICG) by using multi-diameter single fiber reflectance / single fiber

fluorescence (MDSFR/SFF), to correlate these measurements to

signal-to-background ratios based on near-infrared qFME and to explore whether

the extrahepatic biliary anatomy (and the papilla of Vater) is endoscopically

visible by detecting fluorescent signals with ICG-enhanced near-infared qFME.

Study description

Background summary

Endoscopic submucosal dissection (ESD) is a relatively new technique to treat superficial cancers (in the upper gastrointestinal (GI) tract. Previous studies

reported high en bloc resection rates (95% - 97%). However, R0 resection rates (84.5%) suggest that the tumour is not radically removed in all cases, resulting in a risk of tumour recurrence. One of the key challenges is the limited accuracy in determining the depth of cancer invasion. To reduce the risk of tumour recurrence, the endoscopist would greatly benefit from proper and complete visualization of the tumour margin and depth during ESD. Several studies have shown that near-infrared quantified fluorescence molecular endoscopy (qFME) could be served as a red flag detection method and might be useful imaging tool for tumour demarcation in the upper gastrointestinal tract. Since these patients already receive ICG during fluorescence endoscopy, there is a second exploratory research question. Another endoscopic procedure, called ERCP, is used for treating bile duct and pancreatic diseases. This procedure requires successful cannulation of the bile ducts, which fails in 5-20% of cases. ICG is excreted via bile. Therefore, the researchers hypothesize that near-infrared qFME with ICG may aid in better identifying the extrahepatic bile ducts and the entry point from the intestine, the papilla of Vater, as bile flows through this area. Therefore, a secondary, purely observational research question is whether the papilla of Vater and the intraduodenal part of the bile ducts will be endoscopically visible by detecting fluorescent signals after ICG near-infrared qFME.

Study objective

The primary objective is to evaluate the feasibility of ICG-enhanced near-infrared qFME to determine tumour demarcation and tumour depth in upper GI tumours (e.g. HGD or superficial oesophageal and/or gastric adenocarcinoma (T1)) during ESD.

Study design

The current study is a single-centre, non-randomized, non-blinded, feasibility study.

Intervention

Intravenous administration of ICG in combination with near infrared quantified fluorescence molecular endoscopy.

Study burden and risks

For the participating patients, there is no diagnostic or treatment benefit related to the study. Participation may possibly lead to useful data for the future research. The risk of participating in this study is the administration of indocyanine green, an FDA approved dye that has a very low toxicity with a complication rate of 0.05 - 0.07% . Clinical decisions will not be affected or

influenced by the imaging data.

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

- Patients with confirmed high grade dysplasia or superficial esophageal and/or gastric adenocarcinoma (T1) and are scheduled for ESD within the UMCG;
- Age of 18 years or older;
- Able to provide written informed consent

Exclusion criteria

- Contraindications for indocyanine green:
* Known allergy to indocyanine green
* Known allergies to iodine, shells and/or clams
* eGFR < 30 mL/min/1,73 m2
* pregnancy or provides breastfeeding
* Hyperthyroidism

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-04-2025
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

No registrations found.

In other registers

Register	ID
CCMO	NL88635.042.24