Feasibility of endoscopic placement of fiducial markers and marker-based image-guided pre-operative radiotherapy in patients with gastric cancer

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To study the feasibility of endoscopic placement of fiducial markers and of the use of these markers for image-guided preoperative radiotherapy in patients with gastric cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON50759

Source
ToetsingOnline

Brief title
Markers in gastric cancer RT

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Gastric cancer, gastric carcinoma, stomach cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: CT imaging, Endoscopy, Fiducial markers, Radiotherapy

Outcome measures

Primary outcome

Feasibility of using fiducial markers in image-guided pre-operative

radiotherapy for patients with gastric cancer.

Secondary outcome

- Success rate of marker implantation;

- Safety of marker implantation;

- Stability of markers over time;

- Visibility of markers on planning CT and CBCT;

- Ability to use the markers for image registration of CBCT with planning CT;

- Potential benefit of fiducial marker-based image-guided radiotherapy.

Study description

Background summary

In the first half of 2018, the CRITICS-II study will start, a multicenter randomized phase-II trial for resectable gastric cancer (EudraCT # 2015-004627-31). For pre-operative radiotherapy, part of two of the three study arms, the entire stomach with surrounding lymph nodes is included in the clinical target volume. However, the stomach is a highly mobile organ, displaying deformation and motion due to breathing, gastrointestinal filling and peristalsis. Daily CBCT-based patient position verification is used, but visibility of the stomach on CBCT is limited.

We hypothesize that fiducial markers with high visibility on CT and CBCT benefit CBCT-based position verification. This will improve accuracy of pre-operative radiotherapy for gastric cancer patients.

Study objective

To study the feasibility of endoscopic placement of fiducial markers and of the use of these markers for image-guided preoperative radiotherapy in patients with gastric cancer.

Study design

This study is a prospective single-arm intervention study.

Intervention

All included patients will undergo endoscopic placement of fiducial markers in the stomach. In addition, extra imaging will be obtained:
- the daily cone-beam CT scan prior to radiation will be extra long
- weekly, a long cone-beam CT scan will be obtained after irradiation
- in weeks 1, 3 and 5, a CT scan will be obtained.

Study burden and risks

(Burden) Endoscopy-session: if possible this will be combined with the biopsy endoscopy that each patient receives within the CRITICS-II clinical trial protocol. Long CBCT scan: adds 2.5 minutes to the daily treatment time. Weekly post-irradiation CBCT scan: takes place directly after irradiation; adds 4 minutes to the treatment time. In week 1, 3 and 5 a CT scan will be acquired (20*30 minutes per scan): will be planned directly prior to or directly following an irradiation session.

(Risks) For this study extra risks are not to be expected. Like all other endoscopic procedures a bleeding could occur. The infection risk is estimated low, comparable to the risk of bleeding. The risk of bleeding is estimated low and, if occurring, assumed to be small and self-limiting (overall risk <1%). The extra radiation dose from the CT and CBCT scans is small compared to the treatment radiation dose of 45 Gy (<2%).

(Benefit) For each patient, the markers will be taken into account during daily patient position verification / position correction.

(Group relatedness) All included patients are patients with gastric cancer referred for radiotherapy. No minors or incapacitated persons will be included in the study.

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 histologically proven primary gastric cancer;
- Referred for pre-operative radiotherapy in the AMC;
- Written informed consent.

Exclusion criteria

- Coagulopathy or platelets level < 40.000;
- Endoscopic suspicion of fistula;
- Endoscopic suspicion of active gastric infections;
- High risk for sedation;
- Unwilling to participate in the study and/or sign informed consent;
- Pregnant;
- Age < 18 years.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2018
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	VISICOIL gold marker AND/OR BioXmark
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	13-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 27588
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65080.018.18
OMON	NL-OMON27588

Study results

Date completed:	04-03-2022
Actual enrolment:	14

Summary results
Trial is onging in other countries