Pilot study evaluating the feasibility of endoscopy guided fiducial marker placement for rectal cancer.

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This pilot study will evaluate the feasibility of endoscopic guided placement of gold markers in rectal cancer patients including:- Technical success of fiducial marker placement by (EUS guided) endoscopy- Visibility of fiducial markers on MRI and...

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

Summary

ID

NL-OMON41313

Source
ToetsingOnline

Brief title
Endoscopy guided fiducial marker placement for rectal cancer.

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
rectal cancer, rectal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: KWF;zie G2 en J,COOK medical (levering 15

goudmarkers),VISICOIL (levering 45 goudmarkers)

Intervention

Keyword: endoscopy, fiducial marker, radiotherapy, rectal cancer

Outcome measures

Primary outcome

The feasibility of fiducial marker placement, defined as the technical success

(the ability to successfully place the fiducials at the desired locations in

the tumour area, without grade 3-4 complications or symptoms lasting more than

two days), the visibility of fiducial markers on MRI and CT, the migration of

fiducial markers and the patient safety of marker placement.

Secondary outcome

A secondary aim of this study is to evaluate the intrafraction movement of the

rectum as visualized on cone beam CT scan.

Study description

Background summary

Neo-adjuvant radiotherapy - in addition to total mesorectal excision - improves local control of rectal cancer. However, patients experience long-term side effects after neo-adjuvant radiotherapy, such as fecal incontinence and impaired sexual functioning.
A reduction in target volume may lead to less side effects and less treatment-induced mortality. However, target delineation remains difficult for rectal cancer due to poor visibility of the tumour and target coverage is difficult due to tumour motion. Fiducial markers may improve radiotherapy treatment planning and position verification and may provide an opportunity for a reduction in radiotherapy target volume. Fiducial markers are used for position verification in other cancers, such as prostate cancer. The clinical value of fiducial markers in rectal cancer radiotherapy has not been assessed.

Study objective

This pilot study will evaluate the feasibility of endoscopic guided placement of gold markers in rectal cancer patients including:
- Technical success of fiducial marker placement by (EUS guided) endoscopy
- Visibility of fiducial markers on MRI and CT
- Migration of fiducial markers
- Patient safety of marker placement

Study design

Prospective interventional study in the Netherlands Cancer Institute - Antoni van Leeuwenhoek, Amsterdam and the Leiden University Medical Center, Leiden.

Intervention

Patients will undergo an (endoscopic ultrasound (EUS) guided) endoscopy during which two to three gold markers will be implanted in the upper and lower border of the tumour and in the center of the tumour or in the tumour area. Five additional cone beam CT scans and one or two additional MRI scans will be made for evaluation of the fiducial markers.

Study burden and risks

Participation in this pilot study consists of the placement of two to three fiducial markers during an (EUS guided) endoscopy in the week prior to radiotherapy. The procedure will last about 10 minutes and will include very low risks of rectal pain, bleeding or infection after the procedure. In addition to standard imaging for radiotherapy treatment planning and position verification, five additional cone beam CT scans and one or two additional MRI scans, will be made for study purposes.

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

• Histologically proven diagnosis of primary rectal adenocarcinoma
• Treatment plan:
o 5x5 Gray (Gy) neoadjuvant radiotherapy followed by TME
* cT1-3N1 / cT3N0 with extramural invasion >5 mm
* Distance to mesorectal fascia >1 mm
OR
o Chemoradiation consisting of 25 x 1,8 Gy combined with Capecitabine 825 mg/m2 twice daily followed by TME
* cT4 / cT2-3 with distance to mesorectal fascia <=1 mm
and/or
* cN2 / extramesorectal pathological lymph nodes
OR
o 5x5 Gy RT followed by chemotherapy (with or without a subsequent TME)
* rectal cancer with resectable liver metastases
• Written informed consent

Exclusion criteria

• Coagulopathy (prothrombin time < 50% of control; partial thromboplastin time > 50 seconds) or anticoagulantia (marcoumar, sintrom or new oral anticoagulants) that cannot be stopped
• Prior pelvic irradiation or surgery that may affect the placement of the markers
• World health organization performance status 3-4
• Pregnant women
• Patients who underwent a hip replacement
• Patients with a contraindication for MRI (e.g. pacemaker, metallic foreign body in the eye, cerebral aneurysm clips, claustrophobia)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Fiducial marker
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-04-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO Date:	15-01-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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: 20605
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL46483.031.14
OMON	NL-OMON20605