The effectiveness of the placement of gold markers for irradiation of rectal cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20605

Source
Nationaal Trial Register

Brief title
Remark

Health condition

Rectal cancer
Rectumcarcinoom
Endeldarmkanker

Sponsors and support

Primary sponsor: NKI-AVL
Source(s) of monetary or material Support: NKI-AVL

Intervention

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).

Secondary outcome

- Patient safety: grade 3-4 complications (NCI-CTCAE version 4.0) or symptoms lasting more than two days.

- Visibility of fiducial markers on MRI and CT

- Migration of fiducial markers

Study description

Background summary

NA

Study objective

The aim of this study is to evaluate the feasibility of endoscopic guided placement of gold markers in rectal cancer patients.

An effective and safe endoscopic placement of fiducial markers in the rectum may benefit the imaging of the rectal tumor for radiotherapy purposes (position verification and target volume delineation).

Study design

The study participation of the patient will end after the TME.

Intervention

Patients will undergo an (endoscopic ultrasound (EUS) guided) endoscopy during which two to three gold markers will be inserted in the upper and lower border of the tumour and in the center of the tumour.

Five additional cone beam CT scans and one or two additional MRI scans will be made for evaluation of the fiducial markers.

Contacts

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Eligibility criteria

Inclusion criteria

• Histologically proven diagnosis of primary rectal adenocarcinoma

• Resectable rectal cancer

o cT1-3N1 / cT3N0 with extramural invasion >5 mm

o Distance to mesorectal fascia >1 mm

• No evidence of distant metastasis

• Treatment options: 5 x 5 Gray (Gy) neoadjuvant radiotherapy followed by TME; Chemoradiation consisting of 25 x 1,8 Gy combined with Capecitabine 825 mg/m2 twice daily followed by TME; 5x5 Gy RT followed by chemotherapy (with or without a subsequent TME)
• Written informed consent

Exclusion criteria

• Coagulopathy (prothrombin time < 50% of control; partial thromboplastin time > 50 seconds) or anticoagulantia (marcoumar or sintrom) that cannot be stopped

• Prior pelvic irradiation or surgery

• 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
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2014
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-05-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41313
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4473
NTR-old	NTR4606
CCMO	NL46483.031.14
OMON	NL-OMON41313

Study results