Feasibility study of intratumoral gold marker placement and cone beam CT for image- guided radiotherapy in rectal cancer

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON38849

Source
ToetsingOnline

Brief title
Fiducial markers in rectal cancer

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
rectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: maastro clinic - atrium medisch centrum grant

Intervention

Keyword: cone beam CT, goldmarker, image guided radiotherapy, rectal cancer

Outcome measures

Primary outcome

Primary endpoint is the concordance index between observers on kV CBCT

Secondary outcome

Secondary endpoints:

- % of marker loss

- intra-observer variation in GTV localization with and without markers

- tumor movement

- use of goldmarkers for automatic online matching

- development of SIB technique

Study description

Background summary

Organ motion and patient set-up is an important source of error in radiotherapy. A method to correct for patient set-up is Electronic Portal Imaging (EPI). EPI is based on x-ray imaging and aligning the patient to the beam by matching on bone structures. However, soft tissue targets, such as rectum, esophagus, prostate, cervix/ uterus, bladder, liver and breast, are not visible on the x-ray images. Matching on bone structures is not sufficient in these indications because organ motion will not be detected. Although new technologies have implemented kV cone-beam CT into daily image guidance for set-up and organ motion correction, tumors of the large bowel, like rectal cancers are often not easily seen on kV cone-beam CTs due to additional non-tumoral rectal wall thickening. Fiducial markers placed into the upper and lower border of the rectal cancer could therefore substantially simplify the identification of the tumor location and thereby better guide the radiation

treatment.

Study objective

The aim of this study is to establish the use of VisicoilTM fiducial markers and kV cone beam imaging for image guided radiotherapy. Our goal is to develop an accurate technique to correct for inter-fraction organ motion based on fiducial marker based kV cone beam image information of the tumor itself and to theoretically align the radiation boost beam to the target. The final goal is to implement safe tumor dose escalations in the future, thereby improving tumor responses

Study design

This is an interventional, registration and a planning study. The first step in this study is to determine the accuracy and the reproducibility of intratumoral fiducial marker placement for CBCT image guidance. The placement of 3 fiducial markers in the upper and lower border of the rectal tumor will be determined for its accuracy in target definition in CBCT. The inter- and intra- observer variation will be investigated by randomly showing the daily CBCT scans of 3 patients to different observers.
Consecutively, the daily organ and tumor displacement will be analyzed and recorded in the registration study. Finally, the planning study will evaluate the feasibility of dose escalation to the tumor target in a theoretical simultaneous boost treatment.
Finally, the standard TME surgical procedure of the rectal cancer will remove the markers from the body to avoid any long-term side effects of the markers.

Study burden and risks

The additional CBCT scans do not require extra appointments for the patient. One kV CBCT of the pelvis results in a weighted dose of about 22 mSv [18]. Taking into account 2 extra CBCTs three times a week this results roughly in an extra dose of 17 x 2 x 22*10-3 = 0.75 Gy. The reference CT scan is not made for diagnostic purposes, and will in principle not be judged by an experienced radiologist. Furthermore CBCTs will cost extra time for the patient. The acquisition of 1 CBCT costs aproximately 1*30*. This results in an extra time of 3* per fraction.
The main risks of marker placement with endoscopy are bleeding and perforation. These risks are low; the incidence reported in a large screening program using sigmoidoscopy was 0.002% for perforation and 0.03% for major bleeding[19].
No direct benefits are expected for participants in this 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 histological or cytological proven rectal cancer, treated with long course external beam radiotherapy (both conformal and IMRT radiation therapy techniques are allowed)
- Age >< = 18 years
- Have given written informed consent before patient registration

Exclusion criteria

Patients using anticoagulants (platelet aggregation inhibitors and coumarines)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Fiducial Markers
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	23-10-2013
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
Other	clinical trials.gov, registratie volgt nog
CCMO	NL44239.096.13