Real-time in vivo sensor tracking of rectal tumours during colorectal cancer surgery

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Primary: Feasibility of an in-house developed electromagnetic navigation system during real-time tumour tracking in rectal surgery.Secondary: Evaluation of the accuracy of the system. * Determine the accuracy of the navigation system relative to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON47238

Source
ToetsingOnline

Brief title
Tracked rectal tumour surgery

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
Rectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: NKI-AVL

Intervention

Keyword: Electromagnetic navigation, Rectal surgery, Rectal tumours

Outcome measures

Primary outcome

In this study we aim to evaluate feasibility of the navigation system during real-time tumour tracking in rectal surgery.

Feasibility will be primarily evaluated by judging the successful delivery of interpretable navigation data per procedure. In addition, we will record the extra time needed; the easiness to glue the sensor to the tumour and the satisfactory scores of the surgeons on the additional value of tumour tracking with respect to rigid navigation (N13NAV).

Secondary outcome

Accuracy of the navigation towards anatomical landmarks:

Optical identification of anatomical landmarks are used to validate this accuracy. By hovering the blunt tip probe over the landmarks, post processing can determine the error of the navigated probe tip and the segmented landmarks.

Correlation of navigation with echography:

The outcome measure will be a difference in distance (mm) where the navigation system measures the location of the distal tumour border from the sutures/clips on the excised rectum specimen and the same distance is measured with ultrasound.

Study description

Background summary

Image-guided navigation surgery allows for full utilization of pre-operative imaging during surgery, and has the potential of reducing both irradical resections and morbidity. This is the first study to implement a surgical image-guided EM navigation system in which traceable sensors are glued on or near the tumor to provide the surgeons with real-time information on the tumor location and orientation.

Study objective

Primary:
Feasibility of an in-house developed electromagnetic navigation system during real-time tumour tracking in rectal surgery.

Secondary:
Evaluation of the accuracy of the system.
* Determine the accuracy of the navigation system relative to anatomical landmarks during surgery by correlation of probe measurements to visual inspection.
* Determine the accuracy of the distance from the probe tip to the tumour. To determine this accuracy we correlate these results with ultrasound of the excised specimen.

Study design

An observational feasibility study.

Study burden and risks

Because of the nature of this study, we do not expect any adverse events to occur that are related to the intervention. Implantation of fiducial markers in or around the rectum tumor has a small risk of bleeding. The patient is monitored for 30 minutes after implantation. Risks by elongation of the procedure time and anaesthesia are small. The success or failure of the sensor placement does not influence the procedure. Measurements shall only be performed during the scheduled operation under full anaesthesia and physical monitoring.
Collected data will not be provided to surgical physicians. Moreover, planned surgical procedure will not be influenced by the measurements and hence patient treatment will not be influenced by the measurements. Subjects who participate in the study will not benefit, nor experience unacceptable additional discomfort.

Participation in the study might involve one or two additional visits to the hospital for the included patients for marker implantation and due to challenging CT scheduling. The investigators will try to minimize the additional visits and plan the scan on the same day as other appointments. Patients will be informed for the study during the pre-operative outpatient clinic appointment. Informed consent will be obtained before implantation of the markers is performed. The total burden for the patient will be one additional contrast enhanced CT scan, one or two XPerCT scans depending on the procedure, glueing of the sensor on or near the tumour with a retractor or proctoscope and an extension of the total surgery procedure with maximally 20 or 30 minutes depending on the amount of XperCT scans.

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

* The patient is planned for rectal surgery by laparotomy or laparoscopy
* The tumour should be within 10 cm of the anal verge
* Signed informed consent
* Patients * 18 years old

Exclusion criteria

* Patients with metal implants in the pelvic area
* Patients for which it is impossible to do a rectal examination

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-11-2016
Enrollment:	21
Type:	Actual

Ethics review

Approved WMO

Date:	31-08-2016
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO Date:	09-08-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	12-07-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	18-09-2018
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: 25173
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL57251.031.16
OMON	NL-OMON25173

Study results

Date completed:	31-08-2019

Actual enrolment:	31