Real-time in vivo rectum tumor tracking using image-guided navigation in colorectal cancer surgery

Published: 07-05-2021
Last updated: 21-09-2024

Accuracy and usability of the navigation setup during rectal surgery.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON50779

Source
ToetsingOnline

Brief title
Navigation in rectal tumor surgery

Condition

- Other condition

Synonym
rectum tumor

Health condition

rectum tumor chirurgie

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: navigation, rectal cancer

Outcome measures

Primary outcome

Determine the accuracy of the navigation setup.

Secondary outcome

To evaluate the usability of the system using post-operative questionnaires for

the surgeons.

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 caused by damaged surrounding structures. This is a feasibility pilot study towards clinical implementation of a new navigation setup in which we can track the tumor within the rectum during surgery.

Study objective

Accuracy and usability of the navigation setup during rectal surgery.

Study design

Before the start of the surgery, the patient will undergo a rectoscopy during which two commercially available medical navigation sensors (Beacon® Transponders) will be implanted inside the mesorectal fat adjacent to the tumor. After implementation of the Beacon® Transponders, a standard pre-operative CT-scan of the pelvic area is acquired in the OR, to determine the location of the Beacon® Transponders with respect to the tumor.
During surgery, an in-house developed surgical navigation setup is placed close

to the patient, i.e. location of the tumor. The surgeon will have a pointer that allows to determine the location of this pointer with respect to the implanted transponders and thus tumor. The surgeon will place standard surgical clips on the resection plane during surgery. The position of these clips are saved by touching the clips with the pointer tip. After the specimen is excised, it will be probed using the navigation setup to acquire additional ex vivo distance measurements. These distance measurements will be compared to pathology measurements to determine the accuracy of the navigation setup. All included patients are already scheduled for rectal surgery. The programmed surgical procedure will not in any way be influenced by the measurements, other than an extension of total operating time by a maximum of 20 minutes.

Study burden and risks

Burden low: marker implantation and CT scan

Risc low: Based on the HFMEA light, the potential risk was classified as *low*, since the maximum risk-score was only 18 (on a scale 0-100).

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL

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 low anterior resection (LAR) or abdominoperineal resection (APR)
• Rectal tumors (based on preoperative imaging)
• Signed informed consent
• Patients >= 18 years old

Exclusion criteria

• Patients with a pacemaker
• 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:	Will not start
Enrollment:	29
Type:	Anticipated

Ethics review

Approved WMO Date:	07-05-2021
Application type:	First submission
Review commission:	METC NedMec

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
CCMO	NL75929.031.20

Study results

Actual enrolment: 0

Summary results
Trial never started