

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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22228

Source

NTR

Brief title

NL75929.031.20 / N20WRS

Health condition

Rectal tumor

Sponsors and support

Primary sponsor: none

Source(s) of monetary or material Support: internal

Intervention

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

Feasibility pilot study towards clinical implementation of a new navigation setup in which we can track the tumor within the rectum during surgery.

Study design

Primary outcome:

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 navigation 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.

Secondary outcome:

The usability of the system is assessed by post-operative questionnaires for the surgeons

Contacts

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Eligibility criteria

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 non invasive
Intervention model: Other
Allocation: Non controlled trial
Control: N/A , unknown

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-07-2021
Enrollment: 29
Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:

Not applicable

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
NTR-new	NL9432
Other	METC : METC20.1194

Study results