LoCAlly advanced and recurrent Rectal cancer NAVigationAL surgery 2.0

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Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON57188

Source
ToetsingOnline

Brief title
CARNAVAL 2.0

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
'Locally advanced rectal carcinoma' and 'a rectal tumor with extension into surrounding tissues'

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: computer-assisted, Image-Guided Surgery, Laparoscopy, Rectal neoplasms, Surgery

Outcome measures

Primary outcome

The primary ouctome measure is the accuracy of stereotactic navigation defined by the distance between predefined anatomical landmarks that are pointed out by means of a tracked instrument by the surgeon intraoperatively (and marked on the transverse, coronal and sagittal MRI images if applicable) and the actual location of this anatomical landmark in the scan that is marked pre-operatively.

Secondary outcome

Secondary outcome measures include: the accuracy of stereotactic navigation, defined by the distance between the pre-determined anatomical reference points intraoperatively identified by the surgeon using a navigation system-calibrated instrument, and the actual location of this anatomical reference point in the scan. The results of a questionnaire assessing the user-friendliness of the navigation system are also considered as secondary outcome measures.

Study description

Background summary

The current rate of incomplete resections in the treatment of locally advanced and recurrent rectal carcinoma is unacceptably high: approximately a quarter and over half of the resections, respectively. This results in a significant risk of metastasis and has negative implications for life expectancy, quality of life, healthcare efficiency, and medical capacity. Achieving a 'radical'

resection, where no tumor cells are left behind, is the key factor for successful long-term survival.

Currently, surgeons determine the route for tumor removal prior to surgery based on their analysis of magnetic resonance images (MRI), without guidance during the operation. There is no available tool to check during surgery whether all tumor cells have been removed.

After a thorough scientific preparation involving various studies, we have currently treated 8 out of 10 intended patients at UMCG using image-guided navigation according to the CARNAVAL 1.0 protocol (locally advanced and recurrent rectal cancer navigation). In brief, before surgery, the tumor and vital structures are highlighted in MRI images, and a plan is created. During surgery, the tip of a rigid surgical instrument is calibrated, which can be used by the surgeon in real-time and whose location is displayed on the scan images to guide the surgeon according to the plan along the tumor and vital structures. The preliminary results are promising. Particularly in cases of locally advanced and recurrent rectal carcinoma, where the tumor has infiltrated surrounding tissues and cannot be operated along anatomical planes, there seems to be added value.

Study objective

Within the framework of the CARNAVAL 2.0 project, this technique is applied to a larger group of 30 patients by multiple surgeons. The primary goal of the study is to determine the oncologic resection rate with a tumour-clear resection margin and radical (R0, margin of >=1 mm) resection rate in patients with a primary cT4bN0-2 locally advanced rectal or recurrent rectosigmoid cancer whoand meeting the selection criteria, when optical stereotactic navigation is applied in combination with 3D MRI topography is applied during the oncologic resection. Theis results will be compared to those of a historical case-matched cohort.
Secondary Objectives:
1) To determine the accuracy of optical stereotactic navigation defined by the distance between the corresponding location in the scan when several anatomical landmarks are pointed out by the surgeon using a tracked instrument and the actual location of this anatomical landmark in the scan.
2) To optimize the workflow
3) To provide training to other rectal surgeons in the utilization of optical stereotactic navigation combined with 3D MRI topography during oncologic treatment for patients diagnosed with these tumors
4) To evaluate user satisfaction with this type of image-guided surgery

Study design

Monocenter, interventional, prospective, longitudinal clinical study.

Intervention

Calibration of the position of the patient in the operating theatre and that of the tip of a surgical instrument by using a c-arm.

Study burden and risks

The risks for the participating patients include:
- Extra radiation exposure of maximal 3.6 mSv (maximum of 3 3D runs c-arm).
- Reduced surgical precision in case of malfunctioning navigation system or incorrect registration and unawareness by the surgeon with an associated increased chance at iatrogenic injury or irradical resection.
However, with a yearly background radiation of ~2,5 mSv, 3.6 mSV is only a limited amount of radiation and too small to demonstrate an association with the occurrence of cancer or congenital defects. Additionally, the application of surgical navigation systems are well expected to improve the quality of surgery for rectal cancer as shown when used in other contexts, especially when combined with 3D MRI-topography.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Patient signed and dated informed consent prior to study-specific screening procedures
2. Primary cT4bN0-2 locally advanced rectal cancer or recurrent rectal cancer or recurrent colonic cancer at colorectal anastomosis with radiologically (potentially) involved margins beyond the mesorectum including pelvic side wall, presacral fascia, sacrum, prostate or vesicles with an indication for resection after neoadjuvant treatment
3. Age >= 18 years

Exclusion criteria

1. Threatened anterior circumferential resection margin negated through the performance of a (posterior) pelvic exenteration
2. Only involvement of the wall of the vagina and/or uterus
3. Tumor involvement sacrum cranial to the junction of S2/S3 and cT4b
4. Tumor involvement of common or external iliac artery/vein
5. Tumor involvement of hypogastric artery bilaterally
6. Tumor involvement of the lumbosacral plexus, sacral nerve 1 or sacral nerve 2
7. Synchronous peritoneal metastases
8. Multifocal recurrence with more than 3 suspected localizations
9. Synchronous suspected metastases in >= 2 different organs
10. Patient operated in semi-elective or acute setting
11. Patient classified as American Society of Anaesthesiologist Class >= 4
12. Patient is unable to speak Dutch
13. Legally incapable

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2023
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Curve 1.2 Dual Navigation Station
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	24-08-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL85118.042.23