Quality assessment of intra-operative radiotherapy in Locally Advanced or Recurrent Rectal Cancer with the use of Image-Guided Navigation

Published: 19-04-2024
Last updated: 02-12-2024

Evaluation of IORT accuracy and effectiveness during rectal cancer surgery by determining the exact position and direction of the IORT beam through the use of an intra-operative electromagnetic image-guided navigation system.

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

Summary

ID

NL-OMON56733

Source
ToetsingOnline

Brief title
QUART

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
colorectal cancer, Rectal cancer, rectal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Intern gefinancierd onderzoek.

Intervention

Keyword: Image-guided surgery, Intra-operative radiotherapy, Rectal Cancer, Surgical navigation

Outcome measures

Primary outcome

The primary endpoint of this study is in-field local recurrence during 3-year

follow-up.

Secondary outcome

- R0-R1 resections and tumor extensiveness.

- 3-year overall survival, 3-year disease-free survival, 3-year local

recurrence-free survival.

- Early (<=30 days) and late (>30 days) complications (Clavien-Dindo) and

toxicity (NCI-CTCAE v5.0).

- Evaluation of the accuracy of the navigation system;

- Evaluation of possible improvements of the navigation hardware and software,

especially the handling in preparation towards andduring surgery (extra time

needed to use the navigation system during abdominal surgery will be recorded);

- Evaluation of the potential influence of the navigation system on

intra-operative decision making.

Study description

Background summary

In recent years, intraoperative radiotherapy (IORT) is increasingly being used for the treatment of rectal cancer. However, the efficacy and safety of IORT for the treatment of rectal cancer remains disputed. Some benefits are seen in the 5-year local disease control, but these results failed to reach statistical significance, thus the exact value of IORT remains to be established by further research. In addition, in these studies, information on the exact localisation and subsequent alignment of the IORT beam is lacking, leading to the inability to draw significant conclusions from studies for IORT use in rectal cancer surgery. This particular study will mainly focus on quality assessment of IORT by visualisation, marking and documentation of the exact position and direction of the beam with the use of a navigation system. This will allow for more feasible comparison of studies using IORT in the future.

Study objective

Evaluation of IORT accuracy and effectiveness during rectal cancer surgery by determining the exact position and direction of the IORT beam through the use of an intra-operative electromagnetic image-guided navigation system.

Study design

An interventional study.

Intervention

A medical device (navigational setup) will be used during surgical resection + IORT procedures in patients with locally advanced and recurrent rectal carcinoma as surgical tool during the resection and for documentation of the exact IORT beam location and direction. Endpoints will be compared with a retrospective cohort based on previous results from the NKI-AvL.

Study burden and risks

No extra noticable burden for the patient. Possibly slightly longer operation (max. 15 mins.) required for setting up and checking the navigation system, which is a negligible extension of the relatively long operation duration for these patients. The only risk is that the system does not function according to set accuracy limits or shows errors during treatment. This will be monitored constantly during the operation. In the exceptional case that such errors cannot be resolved immediately, the surgeon can proceed using the conventional surgical procedure without use of the medical device.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patiënt will be treated for locally advanced or recurrent rectal cancer.
• Treatment plan consists of laparotomy with intra-operative radiation therapy.
• Patient has suitable (contrast-enhanced) CT and/or MRI-scan available.
• Patient is older than 18 years.
• Patient provides informed consent to participate in the study.

Exclusion criteria

• Inclusion criteria are not met.
• Metal implants in the pelvic area.

• Pacemaker and/or cardiac defibrillator implanted.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-05-2024
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	Intra-operative navigationsysteem
Registration:	No

Ethics review

Approved WMO

Date:	19-04-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL86388.100.24