Real-time tracking of rectal tumours during colorectal cancer surgery

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25173

Source
NTR

Brief title
NA

Health condition

Open or laparoscopic surgery for rectal cancer patients

Sponsors and support

Primary sponsor: The Netherlands Cancer Institute –Antoni van Leeuwenhoek Hospital
Source(s) of monetary or material Support: The Netherlands Cancer Institute –Antoni van Leeuwenhoek Hospital

Intervention

Outcome measures

Primary outcome

The primary outcome of this study was feasibility. Feasibility was defined as successful completion of the whole investigational workflow resulting in continuous delivery of interpretable navigation data for rectal surgery.

Secondary outcome

The secondary outcome was accuracy of the system.

Study description

Background summary

Image-guided navigation surgery allows for full utilization of pre-operative imaging during surgery. It has the potential of reducing irradical resection margins and reducing morbidity caused by damaged surrounding structures. We have developed a navigation system that can take positional changes of the tumour into account by using a tracking sensor fixed to the tumour or its surrounding tissue. This is a feasibility pilot study towards clinical implementation of this new navigation system.

Study objective

Image-guided navigation surgery allows the optimal use and full integration of pre-operative images during surgical procedure. This feasibility study investigates the potential of this new technique in surgery in rectal surgery.

The hypothesis is that with navigation surgeons have a better insight in the anatomy of the patient. This will improve the decision making, and can potentially also speed up the procedures. Ultimately, sugical outcome in terms of radicality and morbidity can be improved.

Study design

N/A

Intervention

Use of an electromagnetic navigation system to improve insight and orientation during pelvic surgery.

Contacts

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Eligibility criteria

Inclusion criteria

≥ 18 years

A rectal tumour within 10 cm of the anal verge (based on preoperative imaging)

A signed informed consent

Suitable for contrast enhanced CT scanning

Planned for low anterior resection (LAR) or abdominoperineal resection (APR)

Exclusion criteria

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
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2016
Enrollment:	31
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-04-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47238
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7666
CCMO	NL57251.031.16
OMON	NL-OMON47238

Study results