Image-guided navigation during abdominal surgery

Published: 23-08-2013
Last updated: 19-03-2025

Primary Objective:Feasibility and safety of an in-house developed electromagnetic navigation system during abdominal surgery.Secondary Objectives: Evaluation of the accuracy of the system. Evaluation of possible improvements of the navigation...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON47658

Source
ToetsingOnline

Brief title
Navigation 1 Study

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
abdominal tumors

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: NKI-AVL

Intervention

Keyword: abdominal tumors, adbominal surgery, electromagnetic navigation, rectal surgery

Outcome measures

Primary outcome

Faesibility and safety of an electromagnetic navigation system during abdominal surgery.

Secondary outcome

Evaluation of the accuracy of the system. Evaluation of possible improvements of the navigation hardware and software, especially the handling in preparation towards and during surgery. We will also use the navigation system to localize rigid tumor deposits to gain insight in possible clinical trials.

Study description

Background summary

Identification and sparing of the iliac vessels and ureters during abdominal cancer surgery leads to decreased morbidity rates.

Study objective

Primary Objective:
Feasibility and safety of an in-house developed electromagnetic navigation system during abdominal surgery.
Secondary Objectives:
Evaluation of the accuracy of the system. Evaluation of possible improvements of the navigation hardware and software, especially the handling in preparation towards and during surgery.

Study design

An observational registration study.

Study burden and risks

Participation in the study will not involve additional visits to the hospital for the included patients. Informed consent will be obtained during the pre-operative outpatient clinic appointment or upon admission to the hospital at least one day before operation.
One day before surgery, when patients are already admitted to the hospital, a contrast-enhanced CT-scan of the abdomen is performed. During the scan three removable electromagnetic reference-marker patches are placed on the skin at superficial bony structures of the pelvis, such as the anterior superior iliac spine. The CT scan will be used to create a three-dimensional anatomical reconstructions of the organs at risk within the pelvis. Before surgery, the reference-markers will be positioned at the same locations. The reference-markers will be used during surgery to correlate the CT scan to the actual patient position. An intra-operative CT scan will be acquired to validate and improve the reference marker registration. During surgery, the iliac vessels and ureters will be identified using the guidance of a blunt tip probe of the navigation system. Total time of the proposed measurements will take no longer than 20 minutes. It is highly unlikely that the iliac vessels and ureters will be damaged during this procedure, since the navigation procedure is aimed at sparing these structures. When the abdominal tumour is rigid, e.g. sacral invasion, or when pathological lymph nodes are present outside the standard total mesorectal excision region, the navigation system will be used to localize these structures too. This is a pilot study to evaluate the overall performance of the surgical navigation system during abdominal surgery, without impact on the surgical procedure itself. However, if available, the appointed locations of malignant tissue based on navigation will be cross-correlated with pathology. The eventual goal of this project is to implement the navigation system to reduce the risk of damage to healthy structures and more radical abdominal surgery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

•Patients who are scheduled for a abdominal surgery by laparotomy
•Patients should be suitable for contrast enhanced CT scanning
•A signed informed consent
•Patients >= 18 years old

Exclusion criteria

•Patients with metal implants in the pelvic area

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2014
Enrollment:	95
Type:	Actual

Ethics review

Approved WMO Date:	23-08-2013
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	23-01-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	10-12-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	15-10-2015
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	30-03-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	25-10-2018

Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23132
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL43553.031.13
OMON	NL-OMON23132

Study results

Date completed:	01-02-2020
Actual enrolment:	95