Tracking of liver metastases during surgery

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Primary Objective:To measure distances between the pointer tip held on surgical clips placed on the liver surface and the closest tumor border using navigation, and compare it to the actual distance measured in intraoperative XperCT. Secondary...

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

Summary

ID

NL-OMON45967

Source
ToetsingOnline

Brief title
Liver navigation 1

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
Liver metastases

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Electromagnetic navigation, Image segmentation, Liver cancer

Outcome measures

Primary outcome

To measure distances between the pointer tip held on surgical clips placed on the liver surface and the closest tumor border using the navigation, and to compare it to the actual distance measured in contrast-enhanced intraoperative XpercT (see measurement description).

Secondary outcome

* To assess the feasibility of intraoperative XperCT acquisition and registration to preoperative imaging. Feasibility is judged in visual inspection of similarity of the vessels and lesions on the images.

* To determine the accuracy of the navigation system relative to anatomy before the start of liver surgery (liver border measurement) (in mm).

* To evaluate the usability this the newly introduced technique for users (i.e. surgeons and surgical assistants).

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. This is in liver surgery the first pilot study towards clinical implementation.

Study objective

Primary Objective:

To measure distances between the pointer tip held on surgical clips placed on the liver surface and the closest tumor border using navigation, and compare it to the actual distance measured in intraoperative XperCT.

Secondary Objectives:
* To assess the feasibility of intraoperative XperCT acquisition and registration to preoperative imaging. Feasibility is judged in visual inspection of similarity of the vessels and lesions on the images.
* To determine the accuracy of the navigation system relative to anatomy before the start of liver surgery (liver border measurement).
* To evaluate the usability this the newly introduced technique for users (i.e. surgeons and surgical assistants).

Study design

An observational pilot study.
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.
The standard preoperative contrast-enhanced diagnostic CT or MR-scan is used for preoperative image segmentation to create a three dimensional model of the liver. Important structures like the portal vein, hepatic vein, gall bladder, cysts, ribs and tumor will be delineated. When the patient enters the OR, three external patient trackers containing electromagnetic sensors are placed on the back of the patient. Next, surgery starts according to the standard surgical procedure. When the liver is mobilized, a single 6 degrees of freedom electromagnetic marker is glued to the liver with medical glue in close proximity to the expected location of the tumor. This reference*sensor will be used during the surgery to track the current anatomical position of liver. Additionally, up to four surgical clips are placed within the intended resection area, they will be used for accuracy verification of the system. After this, an intra*operative contrast-enhanced breath hold XperCT scan will be acquired to enable registration based on hepatic vessels of the preoperative MR scan and the current anatomical position of the patient. During this CT-scan, EM tracking will measure the current orientation of the EM sensor. During surgery, anatomical structures will be identified using the guidance of a blunt tip probe of the electromagnetic navigation system. Total time of the proposed measurements, including the intraoperative scan, will take no longer than 30 minutes. This is a pilot study to evaluate the overall performance of the surgical navigation system during surgery, without impact on the surgical procedure itself.

Study burden and risks

Safety issues: No expected risks for the included patients are expected. A

similar approach for abdominal surgery was evaluated in 25 patients (N13NAV) and no potential risks for patients were identified during the course of the study.

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

- Age * 18
- Liver metastases superficial in the liver
- Patients scheduled for liver surgery
- Patients Provide written *informed consent*
- Patients should be suitable for contrast enhanced CT scanning (GFR>60 and no known allergies to iodinated contrast agents)

Exclusion criteria

- Metal implants in the abdominal or thorax area.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-09-2016
Enrollment:	53
Type:	Actual

Medical products/devices used

Generic name:	Navigation system
Registration:	No

Ethics review

Approved WMO Date:	30-05-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-03-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	12-01-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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: 25239
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL56647.031.16
OMON	NL-OMON25239

Study results

Date completed:	28-12-2018
Actual enrolment:	36