Ultrasound-based navigation during liver resection

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON51512

Source
ToetsingOnline

Brief title
Ultrasound-based navigated liver resection

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
liver cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Liver surgery, Navigation, Ultrasound

Outcome measures

Primary outcome

The main study endpoint is the feasibility of ultrasound-based navigation for assistance during hepatic resection. The navigational workflow is deemed feasible when 70% of the navigations are successful. A navigation is successful when instruments can be accurately shown with respect to the 3D model of the resection plane. This is measured by comparing the distance between the navigated pointer at the resection plane (shown by the navigation system) and that same distance measured by postoperative imaging of the resected specimen.

Secondary outcome

1. The easiness of use during surgery using standardized System Usability Scale (SUS) questionnaires amongst the surgeons, together with a questionnaire regarding expected effects on clinical outcome.

2. The time of all study-related actions during the surgery, such as tumour delineation and verification.

3. The difference between the planned resection margin and actual resection margin.

Study description

Background summary

Image-guided navigation surgery allows for optimal use and full integration of 3D models based on patient-specific anatomy. Where image-guided techniques have

proven to be useful for localization and visualization of lesions, accurate guidance during the process of liver resection has not been accomplished yet. Previous image-guided techniques use preoperative 3D models which in liver surgery are not up-to-date due to liver tissue deformation. This is the first feasibility study where navigation is based on 3D models based on intraoperative ultrasound imaging.

Study objective

The primary objective of this study is to assess the feasibility of ultrasound-based navigation for assistance during hepatic resection. Secondary objectives are 1) to evaluate the ease of use and support for decisiveness during surgery, 2) to evaluate the time of all study-related actions during the surgery, and 3) the difference between the planned resection margin and actual resection margin.

Study design

Single center feasibility study. The duration of the study will be one year.

Intervention

The patient is operated on a surgical bed with a field generator positioned under the bed or near the head of the patient. The surgical procedure will start according to the standard practice. After obtaining access to the target lesion, a sensor is attached close to the targeted tumour and a 3D ultrasound volume is acquired. After semi-automatic segmentation of this US volume, the tumour and surrounding vasculature are visualized on a display, together with the navigated surgical instruments. Surgical clips are placed during the resection and are pointed at with the navigated pointer to measure distances. Resection of the tumour continues afterwards.

Study burden and risks

Participation in the study will not involve additional visits to the hospital for the included patients. The patients will be recruited in the NKI-AvL. Patients will primarily be informed about the study during the pre-operative outpatient clinic appointment by the treating surgeon. Extensive explanation is consequently provided by the researcher. If time between the outpatient clinic visit and the scheduled operation date is limited, the patient will be contacted by telephone to provide them with enough time to consider participation in the study. After 10 working days, the researcher will contact the patient by phone to answer questions. If patients approve to inclusion, written informed consent will be obtained by the researcher before or at admission to the hospital before the operation.
Surgical decision making takes place based on conventional 2D ultrasound, the

navigation system is only used for accuracy evaluation. A maximal delay of approximately 15 minutes will be added to the total time of the surgical procedure. The surgeons are aware of the experimental setup, and are therefore responsible for the navigation interpretation and actions. The ultimate goal of this project is to judge the potential use of the navigation setup for further liver resections.

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 years
- Patient provides written informed consent form
- Patient is scheduled for liver resection

Exclusion criteria

- Ferro-magnetic implants in the abdominal or thoracic area that could influence electromagnetic tracking or the electromagnetic field
- Pacemaker
- Non-visible lesions on intraoperative ultrasound imaging

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-10-2022
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	navigation system
Registration:	No

Ethics review

Approved WMO Date:	28-07-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	27-11-2024

Application type:	Amendment
Review commission:	METC NedMec

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	NL80634.031.22