Ultrasound-based navigation during liver surgery

No registrations found.

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

Summary

ID

NL-OMON29374

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Liver lesions from any origin

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

Accuracy of the navigation system, calculated with the target registration error. In group 2, additional target registration error is calculated for the needle placement.

Secondary outcome

- Assess registration accuracy of vessel structures in the surroundings of the liver lesions.
- Second, the time that is needed for registration and the total time added to surgery are assessed as efficiency measures. The time that is needed for positioning of the ablation needle is recorded as well.
- Assess the time for registration and the total time added to surgery, time for needle positioning and total added time to surgery as efficiency measures.
- Evaluate usability of the newly introduced technique for surgeons with questionnaires

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 ablations, and morbidity. This is a first feasibility study towards clinical implementation of ultrasound-based navigation during liver surgery.

Study objective

The aim of this study is to develop and evaluate a new ultrasound-based navigation system for guidance of resection and
ablation of liver lesions during liver surgery. The feasibility and accuracy of this in-house developed navigation system is
assessed during intraoperative use. A clinical workflow is set up for use during open surgery. The accuracy of registration
between intraoperative 3D ultrasound and preoperative images is assessed by means of the target registration error of selected
liver lesions.

Study design

N/A

Intervention

Procedure:
Participation will not involve additional visits to the hospital for the patients. Informed consent will be obtained during preoperative outpatient clinic appointment or upon admission to the hospital at least one day before operation.
Prior to the surgery, a patient-specific 3D liver model, including the liver contour, hepatic vasculature and target lesions, is created from diagnostic MR images. This 3D model is used for navigation during resection (group 1) and ablation (group 2) in open surgery. On the day of the surgery, the surgical procedure will start according to the standard practice. After the laparotomy, a single 6 degrees of freedom electromagnetic (EM) marker is placed on the

surface of the liver near the targeted lesion. This marker is used to record the exact location of the organ throughout the procedure. Subsequent, the surgeon performs an ultrasound sweep near the target lesion, that will be used to create a 3D ultrasound image of the organ. The liver is registered to the diagnostic MRI and the 3D model, and the targeted lesion is selected in the navigation system. Registration takes place manually (phase I) or automatically (phase II). The registration accuracy is assessed with the target registration error.
In case of ablation, the tracked ablation needle is placed according to the standard protocol. Just before the start of the ablation, a secondary ultrasound sweep is performed, visualizing the tumor and the tip of the RFA/MWA needle. This volume will be used to assess the accuracy of the automatic registration and the accuracy of the needle placement. After this, surgical resection continues according to the standard protocol.

Contacts

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Eligibility criteria

Inclusion criteria

- Age ≥ 18 years
- Patient provides written informed consent form
- Patient is scheduled for open liver resection and/or ablation
- Presence of at least one centrally located liver lesion
- Contrast-enhanced MRI or CT scan not older than 2 months
- Lesion diameter under 8 cm
- Lesion located within 5 cm of the liver surface

Exclusion criteria

Metal implants in the abdominal or thoracic area that could influence electromagnetic tracking or other influences
that would influence the electromagnetic field
- Isoechoic liver lesions or lesions with a complete radiological response
- Pregnancy
- Pacemaker
- Presence of large cysts (> 5 cm in diameter) near the target liver lesion
- Diagnostic scan older than 2 months at time of surgery

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2018
Enrollment:	92
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	07-08-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54731
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7951
CCMO	NL65724.031.18
OMON	NL-OMON54731

Study results