Navigation for percutaneous liver ablation

Published: 03-02-2025
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The primary aim of this study is to assess the feasibility of EM-navigation for percutaneous liver ablation.

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

Summary

ID

NL-OMON57277

Source
ToetsingOnline

Brief title
Navigation for percutaneous liver ablation

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
liver lesions, 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 lesions, Percutaneous ablation

Outcome measures

Primary outcome

The main study endpoint is the feasibility of our in-house developed navigation system for percutaneous liver ablation. The study is considered feasible when 70% of the navigations are successful. A navigation is successful when the ablation antenna is accurately visualized with respect to a registered 3D model of the target lesion. An error between the determined position in the 3D model and the actual position of the ablation needle as determined by a standard verification CT scan of less than 10 mm is regarded accurate. 10 mm is regarded as sufficient, as the total volume of the ablation zone is 3 cm or larger.

Secondary outcome

• To evaluate easiness of use and support for decisiveness during surgery using stand-ardized System Usability Scale (SUS) questionnaires.

• To evaluate the time of all study-related actions during the surgery.

• To evaluate the accuracy of the registration from the pre-procedural CT to the EM-field with the target registration error (distance tumor center CT - tumor center EM).

• To evaluate the antenna tracking accuracy, which is defined as the distance between the antenna in the US image and in the EM field.

Study description

Background summary

Accurately positioning an ablation antenna for percutaneous liver ablation procedures can be challenging and time consuming. Image-guided navigation surgery allows for optimal use and full integration of 3D models based on patient-specific anatomy. Image-guided techniques have proven to be useful for localization and visualization of lesions in liver surgery, and might be of use for percutaneous liver ablation procedures. Commercially available navigation systems have shown to be too complex or inaccurate, which we aim to improve with this navigation system.

Study objective

The primary aim of this study is to assess the feasibility of EM-navigation for percutaneous liver ablation.

Study design

A single-centre feasibility study.

Intervention

A semi-automatically segmented 3D model from the pre-procedural CT scan, is registered with our EM-field. To achieve this, sensors are sticked to the patient*s skin during the CT scan and will stay in place during the entire procedure. By placing an EM-tracked, rigid cannula onto the ablation antenna we can visualize the ablation antenna relative to the anatomy and the liver lesions. Besides, EM-tracked ultrasound facilitates orientation during the antenna placing procedure. The antenna is placed during breath hold to minimize the influence of the breathing on the position of the liver.

Study burden and risks

Participation in the study will not involve additional visits to the hospital for the included patients. Patients will be informed about the study during the pre-operative outpatient clinic appointment. Informed consent will be obtained during one of the patients visits to the hospital. Antenna placement takes place with conventional decision making, by using ultrasound and CT. The interventional radiologists are aware of the experimental setup, and are therefore responsible for the navigation interpretation and actions. During the procedure, the accuracy of the registration is assessed by checking the overlap of CT based 3D model and the tracked ultrasound. The ultimate goal of this project is to judge the potential use of the navigation setup for percutaneous

liver ablation procedures. A maximal delay of 20 minutes will be added to the total time of the procedure, which is standardly 3 to 4 hours.
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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 or legal representative provides written informed consent form;
- Patient is scheduled for percutaneous liver ablation.

Exclusion criteria

- Ferro-magnetic implants in the abdominal or pelvic area that could influence EM tracking;
- Pacemaker.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	19-01-2025
Enrollment:	29
Type:	Anticipated

Medical products/devices used

Generic name:	Navigation setup Percutaneous liver ablation
Registration:	No

Ethics review

Approved WMO

Date:	03-02-2025
Application type:	First submission
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	NL88039.041.24