# Ultrasound-based navigation during liver surgery

Published: 11-07-2018
Last updated: 19-03-2025

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Hepatobiliary neoplasms malignant and unspecified |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON54731

**Source**
ToetsingOnline

**Brief title**
Ultrasound navigation liver

### Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

**Synonym**
Liver tumours

**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, Ultrasound imaging

## Outcome measures

### Primary outcome

Main endpoint of the study is the accuracy of the navigation system during the surgical procedure. The accuracy of the navigation is calculated with the target registration error (TRE). The target registration error is calculated by measuring the distance between the center of the lesion in ultrasound, and the center of the lesion in the registered diagnostic scan. In group 2, an additional target registration error is calculated regarding the accuracy of the needle placement. This is done by comparing the distance between the needle tip and the center of the lesion in the 3D ultrasound sweep and the same distance in the navigation software. For both accuracy assessment a second ultrasound sweep is performed as gold standard.

In addition, in patients in phase III, undergoing laparoscopic liver resection, the navigation is shown as an overlay onto the laparoscopic video image. Accuracy of this augmented reality is determined visually based on the distance between overlay and video of superficial anatomical landmarks, such as the liver contour, ligaments and superficial tumors.

### Secondary outcome

- Assess registration accuracy of vessel structures in the surroundings of the liver lesions.

- Assess the time that is needed for registration and the total time added to

surgery as efficiency measures. The time that is needed for positioning of the

ablation needle is recorded as well.

- Evaluate usability of the newly introduced technique for surgeons with

questionnaires.

# Study description

### Background summary

Image-guided navigation surgery allows the optimal use and full integration of preoperative images during surgical procedures. Image-guided navigation systems provide a perioperative link between the current location of the organ and diagnostic images, and has the potential of reducing irradical resection and ablations, as well as morbidity. In this study, ultrasound-based navigation is investigated in 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 and laparoscopic 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. In addition, augmented reality visualization of the navigation is tested for laparoscopic liver procedures.

### Study design

A single center observation feasibility study.

This study is designed as a single center observational feasibility study. The duration of the study is 3 years. Patients are subject in this study until the end of the surgical procedure. Patients eligible for inclusion are patients admitted to the Netherlands Cancer Institute - Antoni van Leeuwenhoek, planned to undergo 1) resection of liver lesions in open surgery and/or 2) ablation of one or more liver lesions during open liver surgery. The targeted lesions can be from any origin.

The navigation system is introduced in 28 patients during phase I of the study.

Here, the intraoperative situation is registered manually to the preoperative diagnostic scan. Additionally, in these patients we collect data to develop an automatic registration algorithm.
In phase II, the developed algorithm for automatic registration is used. Firstly, feasibility of this algorithm is tested in an initial group of 5 to 8 patients during surgical resections in open liver surgery. An interim analysis decides whether we proceed with this automatic registration algorithm or if adjustments in the setup are necessary. From now on, phase II is divided in group 1 of 28 patients scheduled for open resection, and group 2 of 28 patients for ablation during open resection.

In phase III, the navigation system will be tested during laparoscopic liver procedures. Similar to phase I of this study, the intraoperative situation is registered manually to the preoperative diagnostic scan. In addition, the navigation will be shown to the surgeon by an augmented reality over the laparoscopic video image. The minimal invasive workflow will be first optimized in 5 patients as a learning curve is expected, after which 28 patients will be included.

**Study burden and risks**

The nature of this study does not cause expectations of any adverse events to occur that are related to the intervention. The electromagnetic tracking system has been used in multiple studies in our institute without any adverse events. The sensor on the liver surface has been used in our institute in over 40 patients of a previous liver navigation study and has not caused any adverse events. Measurements shall only be performed during the scheduled operation under full anaesthesia and physical monitoring. The added time will maximally be 15 minutes, which is added in the total anaesthesia time of a surgical procedure that normally lasts 3 or 4 hours.
The planned surgical procedure will not be influenced by the measurements and the planned radiofrequency/microwave ablation during the surgical procedure will not be influenced by the measurements. Hence, patient treatment will not be influenced by the measurements.
Subjects who participate in the test will not benefit from the test, nor unacceptable additional discomfort will be experienced.

# Contacts

**Public**
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX

NL
**Scientific**
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL

# 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 open liver resection and/or ablation or laparoscopic liver resection
- 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 invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 06-03-2019 |
| Enrollment: | 124 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | Navigation system |
| Registration: | No |

# Ethics review

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| Approved WMO Date: | 11-07-2018 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 15-02-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 13-06-2019 |

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| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 09-06-2022 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 29-08-2023 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 09-01-2025 |
| 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

ID: 29374
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL65724.031.18 |
| OMON | NL-OMON29374 |