Ultrasound-based navigation during liver surgery

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29374

Bron
NTR

Verkorte titel
N/A

Aandoening

Liver lesions from any origin

Ondersteuning

Primaire sponsor: The Netherlands Cancer Institute –Antoni van Leeuwenhoek Hospital
Overige ondersteuning: The Netherlands Cancer Institute –Antoni van Leeuwenhoek Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Accuracy of the navigation system, calculated with the target registration error. In group 2,

additional target registration error is calculated for the needle placement.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2018
Aantal proefpersonen:	92
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	07-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54731
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten