

# Tracking of liver metastases during surgery

Gepubliceerd: 06-02-2018 Laatste bijgewerkt: 19-03-2025

Image-guided navigation surgery allows the optimal use and full integration of pre-operative images during surgical procedure, and has the potential of reducing both irradical resections and morbidity. This pilot study investigates the potential of...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Observationeel onderzoek, zonder invasieve metingen

## Samenvatting

### ID

NL-OMON25239

### Bron

Nationaal Trial Register

### Verkorte titel

NL56647.031.16 / N16LNA

### Aandoening

Open liver surgery, resection margins, surgical navigation

### 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

The main study endpoint is the accuracy of the EM navigation system to measure the

distance from the EM probe (or tumor resection margin) to tumor tissue. In addition we will evaluate the handling of the navigation system during liver surgery.

## **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 morbidity. This is in liver surgery the first pilot study towards clinical implementation.

### **Doel van het onderzoek**

Image-guided navigation surgery allows the optimal use and full integration of pre-operative images during surgical procedure, and has the potential of reducing both irradical resections and morbidity. This pilot study investigates the potential of this new technique in liver surgery.

The objective of this feasibility study is to evaluate the accuracy of an in-house developed electromagnetic navigation system to determine the distance from the resection margin to tumor tissue during liver surgery.

### **Onderzoeksopzet**

N/A

### **Onderzoeksproduct en/of interventie**

On the day of surgery, three reusable electromagnetic (EM) patient trackers are placed on the back of the patient. Additionally, a single 6 degrees of freedom EM reference-marker and three surgical clips are attached to the liver with medical glue in close proximity to the tumor, but within the area that is planned to be removed by a surgery. This reference-marker, which is placed at the start of the surgical procedure, will be used as a beacon for the EM navigation procedure, while surgical clips will be utilized for system's accuracy verification. To subsequently correlate the precise position of the beacon to the pre-operative diagnostic CT or MR images, an intra-operative contrast enhanced breath hold XperCT scan will be acquired once the beacon is in place. The images from this XperCT will be fused with the pre-operative diagnostic CT/MR which allows us to exactly visualize the position of the beacon on the diagnostic pre-operative CT scan.

During the following surgical procedure, anatomical structures and metastatic lesions can be identified using a blunt EM guidance probe of the electromagnetic navigation system. The accuracy of the EM system will be determined by measuring at several spots on the resection plane the distance from the resection plane to tumor tissue. These measurements will

afterwards be correlated to corresponding distances in intraoperative XperCT image, which will be considered as a “gold” standard. Total time of the proposed intra-operative scan, including the planned accuracy measurements of the EM system, will take no longer than 30 minutes. Subsequent resection of the liver tumor will be performed according to standard surgical techniques. This is a feasibility study to evaluate the overall performance and accuracy of the surgical navigation system during surgery, without any impact on the surgical procedure itself.

## Contactpersonen

### Publiek

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The study population exists of patients scheduled for surgery of liver metastases from any origin.

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- ☐ Age  $\geq 18$
- ☐ Liver metastases less than 3 cm under the liver surface
- ☐ Patients Provide written ‘informed consent’

□ Patients should be suitable for iodinated contrast enhanced CT scanning (GFR>60 and no known allergies to iodinated contrast agents)

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

□ Metal implants in the abdominal or thorax area that could influence EM tracking or other influences that would influence the EM field.

## Onderzoeksopzet

### Opzet

Type: Observationeel onderzoek, zonder invasieve metingen  
Onderzoeksmodel: Anders  
Toewijzing: N.v.t. / één studie arm  
**Controle:** N.v.t. / onbekend

### Deelname

Nederland  
Status: Werving gestopt  
(Verwachte) startdatum: 01-05-2016  
Aantal proefpersonen: 53  
Type: Werkelijke startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies  
Datum: 06-02-2018  
Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45967

Bron: ToetsingOnline

Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL6841
NTR-old	NTR7019
CCMO	NL56647.031.16
OMON	NL-OMON45967

## Resultaten

### Samenvatting resultaten

Electromagnetic tracking of liver tumors during open surgical resections

O. Ivashchenko, B. Pouw, K. F. Kuhlmann, R. van Veen, N. F. Kok, E. G. Klompenhouwer, N. Hoetjes, H. C. Groen, J. Nijkamp and TJM Ruers.

SPIE Medical Imaging 2019, Conference 10951 – Image-Guided Procedures, Robotic Interventions, and Modeling, 17-21 February 2019, San Diego, USA

Intraoperative electromagnetic navigation towards liver tumors: a feasibility study

O. Ivashchenko, B. Pouw, R. van Veen, K. F. Kuhlmann, N. F. Kok, E. G. Klompenhouwer, H. C. Groen, J. Nijkamp, TJM Ruers.

Computer Assisted Radiology and Surgery (CARS) Conference 2018, 20-23 June, Berlin, Germany

In vivo identification of liver tumors during liver surgery using electromagnetic navigation: a pilot study

O. Ivashchenko, B. Pouw, J. Nijkamp, K. F.D. Kuhlmann, N. F.M. Kok, E. G. Klompenhouwer, T.J.M. Ruers

Conference of the International Society for Medical Innovation and Technology (iSMIT) 2017, 9-10 November 2017, Turin, Italy.

