Tracking of liver metastases during surgery

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

Samenvatting

ID

NL-OMON25239

Bron
NTR

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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Wetenschappelijk

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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 ≥ 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.