3D preoperative liver resection planning and confirmation

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To assess the feasibility of CT based 3D preoperative resection planning for hepatectomy and postoperative resection confirmation through image fusion of pre- and postoperative 3D CT reconstructions.

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

Summary

ID

NL-OMON57000

Source
ToetsingOnline

Brief title
3D-PreLiveR

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
liver cancer, Malignent liver tumors

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 3D, Hepatectomy, Liver, Preoperative surgical planning

Outcome measures

Primary outcome

Main study endpoint is the feasibility of preoperative planning for surgical resection of liver tumors and the ability to compare post-operative 3D reconstruction of the hepatectomy results to the preoperative 3D surgical planning

Endpoints are:

- The number of patients in which the analysis was possible

- Differences in preoperatively planned resection and margin measurements compared to the achieved resection and resection margins

Secondary outcome

Secondary study endpoints are assessment and correlation of the surgical margins as measured between 3D reconstructions to the histopathological margins, and evaluation of the process of creating the 3D preoperative planning, usability in determining resection plane and the ability to determine post-operative technical success and resection margins.

Endpoints are:

- Volumetric measurements of the resection margins on 3D reconstructions

- Correlation and comparability between histopathological margins and margins measured on 3D reconstructions

- Scoring of process of segmenting and creating the 3D models, and

co-registering and assessing postoperative technical success.

Study description

Background summary

Complete surgical resection is considered one of the main curative treatment options for liver tumors. Complete resection requires clean resection margins, which depends on tumor volume, location, potential to spare sufficient parenchyma and relation to vital intrahepatic structures. A correct assessment of all these factors forms the basis for a well-thought-out plan prior to the operation. In current practice the surgeon prepares for the resection through 2D radiological imaging, i.e. (CE-) CT and MRI scans. The value of cross-sectional imaging for this preoperative planning is great, but translation of 2D images from a regular CT to the 3D intraoperative reality is not easy. The liver is a complex organ with differing anatomy between patients. To better prepare and review the relation between tumor and surrounding tissue, a 3D segmentation and reconstruction can be made from the available imaging. This allows for better visualization of the tumor within the liver and for pre-operative planning of the resection within the parenchyma and distance to critical structures. It is however unknown if the preoperative plan influences surgical technical result and how well the preoperative plan can be adhered.
Additionally, from post-operative CT scans a 3D reconstruction can be made in a similar way. The pre- and post-operative 3D reconstructions and scans can potentially be used to assess adherence to the preoperative plan and evaluate surgical resection margins

Study objective

To assess the feasibility of CT based 3D preoperative resection planning for hepatectomy and postoperative resection confirmation through image fusion of pre- and postoperative 3D CT reconstructions.

Study design

Prospective single center explorative pilot study

Study burden and risks

The participating patients will undergo an additional CECT scan 1-3 days postoperatively during hospitalization after the liver resection surgery. The surgery itself will be performed according to standard procedures. According to the study procedures, an additional pre-operative 3D reconstruction of the CT

will be performed. The 3D reconstruction is based on information already available in the imaging data and will therefore not provide extra information that could otherwise be unknown. The virtual surgical planning will be made by the treating surgeon after the surgery, to prevent influence on the surgery itself.The post-operative CT scan and contrast agents will place extra burden on the patient due to additional ionizing radiation and contrast agents. To ensure the additional contrast agents poses no harm to the patient, poor kidney function (eGFR < 30 mL/min/1.73m2) has been included as an exclusion criterion for participation. The additional radiation dose is thought to be negligible compared to the overall surgical procedure, clinical workup and follow-up of the patients. Total additional radiation dose will be calculated by clinical physicists.

The outcome of this pilot study could provide additional proof of the benefits of 3D preoperative planning for liver surgery and establish the implementation of additional image reconstruction prior to the surgery. This can improve the surgeon's ability to prepare for the surgery and reduce surgery time, reduce risk to critical structures and increase the chance of achieving sufficient margins.

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

Patients who will undergo (partial) liver resection
A contrast enhanced CT scan of sufficient quality for preoperative 3D reconstruction

Exclusion criteria

Prior hepatectomy
Patients unable to undergo additional contrast enhanced imaging, including those with contraindications for CT scans or contrast agents.
<16 years of age

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2024
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO Date:	11-09-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL86289.091.24