Intraprocedural assessment of Ablation Margins using COMPuted tomography co-registration in primary LivEr Tumor treatment with percutanEous ablation: IAMCOMPLETE primary

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To investigate the feasibility of co-registration with MIRADA XD of pre- and post-ablation CT using an optimized scanning protocol. Secondary objectives will be to investigate the reproducibility of CT-CT co-registration, to determine the duration…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON55458

Source
ToetsingOnline

Brief title
IAMCOMPLETE primary

Condition

- Hepatic and hepatobiliary disorders
- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
Hepatocellular carcinoma/ primary liver cancer

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: 3e

Intervention

Keyword: CT coregistration, Image guidance, Percutaneous ablation, quantitative ablation assessment

Outcome measures

Primary outcome

The proportion of patients in whom reliable co-registration with MIRADA RTx of

pre- and post-ablation CT images is feasible

Secondary outcome

1. Inter- and intraobserver variability of CT-CT co-registration to determine

the minimum ablation margin after thermal ablation for liver tumors

2. The time that is required for CT-CT co-registration

3. Percentage of local recurrence per group as categorized according to

ablation margin: <0mm, 0-5mm, >5mm

Study description

Background summary

Percutaneous thermal ablation is a first line therapy for hepatocellular carcinoma (HCC) Barcelona Clinic Liver Cancer stage 0/A. The most frequently used ablation techniques are radiofrequency ablation (RFA) and microwave ablation (MWA).
Compared to surgery, thermal ablation is associated with lower morbidity and mortality, shorter hospital stays and lower costs. Yet, local recurrence rates are higher after thermal ablation compared to resection, especially in HCC >3cm.
A drawback of thermal ablation is that no histological confirmation of

treatment success can be obtained. Treatment success can therefore only be confirmed using medical imaging techniques. In general, a thermal ablation is considered to be successful when post-ablation computed tomography (CT) confirms an area of coagulation necrosis that encompasses the tumor with a margin of at least 5mm in all directions. Currently there is no validated method to accurately determine ablation margins. In general, the interventional radiologist performing the procedure estimates the ablation margins by two-dimensional measurements and visual qualitative assessment of pre- and post-ablation imaging.
Co-registration of pre- and post-ablation contrast enhanced CT allows three-dimensional assessment of ablation margins. In a retrospective study in 103 patients with 110 HCC lesions, CT-CT co-registration was used to determine the minimal ablation margin after treatment with RFA. Only in 2.7% of patients, the coagulation zone encompassed the HCC lesions with a margin of at least 5 mm. Patients with a minimal ablation margin of <3mm had a local tumor progression (LTP) rate of 26.3%, compared to 0% in patients with a minimal ablation margin of at least 3mm.
Unfortunately, co-registration of a pre- and post-ablation CT is often not feasible as the shape of the liver may alter due to differences between the 2 scans in patient position and diaphragmatic excursion.
We aim to investigate the feasibility of a scanning protocol that minimizes errors in co-registration by: 1) performing the contrast-enhanced CT scan immediately before and after the ablation (with the patient in an identical position, under general anesthesia as per usual) and 2) by performing both scans during apnea (after a period of pre-oxygenation). The optimized scanning protocol is expected to allow accurate three-dimensional assessment of margins after thermal ablation.

Study objective

To investigate the feasibility of co-registration with MIRADA XD of pre- and post-ablation CT using an optimized scanning protocol. Secondary objectives will be to investigate the reproducibility of CT-CT co-registration, to determine the duration of CT-CT co-registration, and to investigate the correlation between ablation margins and local recurrence.

Study design

This trial is a prospective, single center, cohort study investigating the feasibility of co-registration with MIRADA XD of CT-scans acquired immediately before and after ablation in patients with BCLC stage 0/A HCC.

Intervention

Patients will undergo thermal ablation under general anesthesia as per usual. A CT with intravenous contrast will be performed immediately before and after the

ablation, while the patient is under general anesthesia. A CT after ablation is standard of practice in the LUMC, but the CT prior to the ablation is a study procedure. Both scans will be performed with the patient in a similar position and during temporary apnea.

Study burden and risks

There are minimal risks caused by the additional contrast enhanced CT scan and the apnea. An additional CT-scan causes higher radiation dose, which is associated to a minor chance of later carcinogenic expression. Contrast agent is associatied to renal dysfunction in exceptional cases. Due to the minimal kidney function as exclusion criteria, we donot expect this to occur. The temporary apnea afte preoxygenation while scanning is not associated with any risks and will be conducted under supervision of the anesthesiologist.

The general risk of this study is estimated very low.

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

1. Age 18 yrs or above
2. HCC very early (0) or early stage (A) according to the BCLC staging system Either de novo or recurrent HCC (prior locoregional therapy is allowed in the study)
3. Candidate for percutaneous thermal ablation as discussed in a multidisciplinary tumor board. Ablation as *bridge-to-transplant* is allowed in the study

Exclusion criteria

1. Estimated GFR <30 ml/min
2. Morbid obesitas or any pulmonary condition that is a contraindication to prolonged apnea and high jet-ventilation
3. Child Pugh C liver status
4. Portal vein tumor invasion
5. Extrahepatic metastasis
6. Uncorrectable coagulopathy
7. Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule
8. Inability or unwillingness to give informed consent

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	23-12-2020
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	23-09-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-03-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL69217.058.19

Study results

Date completed: 09-04-2021

Actual enrolment: 23