PROspective Multi-center study to Evaluate the correlation between safety margin and local recurrence after THErmal ablation USing image co-registration in patients with hepatocellular carcinoma

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25324

Source
NTR

Brief title
PROMETHEUS

Health condition

Hepatocellular carcinoma

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: KWF

Intervention

Outcome measures

Primary outcome

Minimal ablation margin that results in a local recurrence rate <10%

Secondary outcome

- Local recurrence at 1 year after thermal ablation at different categories for minimal ablation margin: <0mm, 0-3mm, 3-5mm, >5mm
- Local & overall recurrence rate, disease-free and overall survival at 1, 2 and 3 years
- Relation between local recurrence at 1 year and disease-free and overall survival

Study description

Background summary

Problem description
Compared to thermal ablation, the complication rate in surgically treated HCC patients is much higher with an odds ratio of 8.24 (95% CI: 2.12-31.95). Yet, surgical resection yields better results regarding local recurrence (HR 0.38 (95% CI: 0.17-0.84)). Therefore, surgical resection remains the treatment of choice for most patients with BCLC 0/A HCC, despite higher morbidity and mortality rates. For thermal ablation to become truly competitive with surgical resection, the issue of local recurrence needs to be addressed.
Ablation systems have predefined algorithms, based on in vitro experiments, to predict size and shape of the ablation. In general, ablations setting are chosen that would result in complete tumor ablation with a safety margin of >5mm, but the actual ablation zone may be smaller than expected and deformed as a result of factors such as inhomogeneous tissue density, liver cirrhosis and heat-sink.
After surgical resection, a pathologist examines the resected specimen to confirm complete resection. After ablation, confirmation of successful ablation can only be obtained using imaging modalities. Currently there is no validated, standardized method to accurately determine safety margins. Most commonly, the interventional radiologist performing the procedure estimates the safety margins by visual qualitative assessment of pre- and post-ablation contrast-enhanced CT (CECT). This method is associated with high interobserver variability and lacks accuracy. There is a need for a method that allows more accurate assessment of safety margins after ablation.

Solution
Over recent years, post-processing software has become available that allows co-registration of pre- and post-ablation CECT. This allows three-dimensional quantitative assessment of ablation margins. Such quantification of ablation margin would allow immediate evaluation of ablation margins and reablation during the same treatment session if margins are deemed to be insufficient. It would potentially be the equivalent of the frozen section that is used for

real-time margin control during surgery.
Retrospective studies have demonstrated the potential value of quantitative assessment of ablation margins after thermal ablation, but this has neither been validated in prospective studies nor in larger patient groups. In a prospective, multi-center, non-experimental study in patients undergoing ablation for BCLC 0/A/B HCC, safety margins will be quantitatively assessed using dedicated co-registration software.
The aim of this project is to correlate ablation margins with outcome to determine the relationship between ablation margins and local recurrence and set the optimal threshold for minimal ablation margin.

Study objective

Over recent years, post-processing software has become available that allows co-registration of pre- and post-ablation CECT. This allows three-dimensional quantitative assessment of ablation margins. Such quantification of ablation margin would allow immediate evaluation of ablation margins and reablation during the same treatment session if margins are deemed to be insufficient. It would potentially be the equivalent of the frozen section that is used for real-time margin control during surgery.

Study design

- Registration
- Ablation
- Follow-up every 3-4 months until 3 years

Contacts

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Eligibility criteria

Inclusion criteria

· Age 18 years or above
· HCC very early (0) or early stage (A) according to the BCLC staging system OR HCC intermediate stage (B) with a maximum of two lesions of ≤5cm each
· Either de novo or recurrent HCC (prior locoregional therapy is allowed in the study)
· Candidate for percutaneous thermal ablation as discussed in a multidisciplinary tumor board
· Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule
· Written informed consent

Exclusion criteria

· Estimated GFR <30 ml/min
· Known severe allergy to contrast medium
· ASA classification higher than 3
· Child Pugh C
· ECOG ≥1 (tumor-related)
· Portal vein tumor invasion
· Extrahepatic metastasis
· Neoadjuvant transarterial therapy (TACE, TAE or TARE), i.e. combination therapy of transarterial therapy with ablation
· Uncorrectable coagulopathy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-08-2021

Enrollment:	165
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-09-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55994
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9713
CCMO	NL75744.058.21
OMON	NL-OMON55994

Study results