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

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

Samenvatting

ID

NL-OMON25324

Bron
Nationaal Trial Register

Verkorte titel
PROMETHEUS

Aandoening

Hepatocellular carcinoma

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: KWF

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

· 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

· 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

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-08-2021
Aantal proefpersonen:	165
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-09-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55994
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten