# Ablation zone delineation with MRI during thermal ablation of liver tumours

Published: 26-02-2019
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To assess the feasibility of real-time MRI temperature monitoring and ablation zone assessment during thermal ablation of liver tumours.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Hepatobiliary neoplasms malignant and unspecified |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON45796

**Source**
ToetsingOnline

**Brief title**
DELIVER

### Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

**Synonym**
Liver cancer, 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:** liver, malignancy, MRI, MWA, RFA

## Outcome measures

### Primary outcome

Primary outcome is the feasibility of real-time MRI temperature monitoring and ablation zone assessment during thermal ablation of hepatic malignancies.

### Secondary outcome

Secondary outcomes are correlation of per-procedural MRI-guided delineated ablation zone with the ablation zone depicted on follow-up CT six weeks after treatment and the predicted ablation zone by manufacturer specifications, and the influence of patient and procedure characteristics on whether the predicted ablation zone is reached.

# Study description

### Background summary

Thermal ablation by radiofrequency (RFA) or microwave ablation (MWA) is a common technique used for local treatment of liver tumours. Successful ablation is dependent of achieving a sufficient temperature rise to induce cell death throughout the tumor, while minimizing heat-induced damage to surrounding tissues. During treatment however, a non-invasive means of temperature feedback is currently unavailable, and therefore intraoperative assessment of treatment efficacy and risk of damage to surrounding tissue is lacking. MRI-guidance of the thermal ablation procedure could enable non-invasive temperature feedback, potentially allowing real-time monitoring of the ablation process and delineation of the true ablation zone during treatment.

### Study objective

To assess the feasibility of real-time MRI temperature monitoring and ablation zone assessment during thermal ablation of liver tumours.

### Study design

Prospective, non-randomized, single centre pilot study.

### Intervention

All patients will receive MRI-guided RFA/MWA treatment of liver tumours with per-procedural ablation zone imaging.

### Study burden and risks

Patients will undergo MR imaging while under general anaesthesia for the ablation procedure. The per-procedural MR imaging is therefore expected to place no direct increased burden on the patients. The needle placement is performed under direct MRI-guidance in a similar methodology as is the current standard in a routine CT-guided procedure. The total time frame of the procedure is expected to be similar to that of a routine CT-guided procedure. However, an additional total anesthesia time of approximately 30 min may be estimated, especially for the first procedures. This is expected to decrease as more experience is gained. Most important risk of the study would be unwanted attraction of metallic objects to the magnet. Such an event would pose hazard to the patient and/or clinical staff members present in the MRI room. To ensure proper management of these risks, an MRI safety checklist will be used. In addition, one staff member will be charged with safeguarding the safe working environment within the MRI room and is required to be present during all procedures. With these safety measures, the additional risk to the patient or operating team is expected to be minimal. Most important potential benefits of intraoperative MR imaging during the ablation therapy are the possibility to assess the percentage of the total tumor volume that is ablated, allowing better insight into the accuracy of the current RFA/MWA treatment. In the future, the feasibility of having MRI-guidance during the ablation could help to avoid per-procedural complications by monitoring of temperatures near adjacent structures-at-risk and allow the ability to visualize the zone of effective treatment, which may hold predictive value for therapy response and patient prognosis.

## Contacts

**Public**
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525GA
NL

**Scientific**
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525GA
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- Age 18 years and over.
- Indication for liver RFA/MWA treatment assessed by the multidisciplinary liver tumor board.
- Written (signed and dated) informed consent.

## Exclusion criteria

- Insufficient command of the Dutch language to be able to understand the patient information.
- Pregnancy
- Contraindications for MRI
- Contraindications for liver RFA/MWA treatment

# Study design

### Design

| | |
|---|---|
| Study phase: | 2 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 16-10-2019 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 26-02-2019 |
| 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 | NL68156.091.18 |