

# Per-procedural ablation zone imaging with MRI during radiofrequency ablation of locally irresectable pancreatic cancer

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To assess the feasibility of real-time MRI temperature monitoring and ablation zone assessment during RFA of LAPC.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Gastrointestinal neoplasms malignant and unspecified
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON45396

### Source

ToetsingOnline

### Brief title

PRECISE: Ablation zone imaging with MRI during RFA of irresectable LAPC

### Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

### Synonym

pancreatic cancer, Pancreatic tumor

### 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:** MRI, pancreatic cancer, RFA

## Outcome measures

### Primary outcome

Primary outcome is to assess the feasibility of real-time MRI temperature monitoring during RFA of locally irresectable pancreatic cancer.

### Secondary outcome

Secondary outcomes are assessment of correlation of per-procedural MRI-guided delineated zone of ablation with ablation effect on CT scan day 7 after RFA and verification on intraoperative MRI of the localization, distance to adjacent structures and position within the tumour of the ultrasound guidance placed needles.

## Study description

### Background summary

In the PELICAN-trial the benefit of intraoperative local radiofrequency ablation (RFA) therapy of irresectable locally advanced pancreatic cancer (LAPC) is investigated in a randomized multicenter phase III clinical trial. Intraoperative RFA of LAPC has been shown to be feasible and safe, but temperature feedback during the ablation procedure is currently lacking. Therefore, the extent of ablation has to be estimated based on modeling and phantom studies and intraoperative assessment of treatment efficacy and complication risks is limited. Intraoperative MR imaging of RFA therapy could provide MRI temperature feedback allowing real-time monitoring of the ablation process and enable delineation of the true ablation zone following RFA therapy.

### Study objective

To assess the feasibility of real-time MRI temperature monitoring and ablation zone assessment during RFA of LAPC.

## Study design

Prospective, non-randomized, single centre pilot study.

## Study burden and risks

Patients will undergo intraoperative MR imaging while under general anaesthesia for the exploratory laparoscopy procedure performed within the PELICAN-trial. The addition of intraoperative MR imaging is therefore expected to place no direct increased burden on the patients. However, total procedure time and anaesthesia time may be longer due to transfer of the patient to and from the MRI suite, which is anticipated at approximately 30 minutes. Most important risk of the study would be unwanted attraction of metallic objects to the magnet, which may be introduced to the MRI environment upon patient transfer. 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 protocol was established. A safety checklist will be used during all procedures to ensure all safety measures have been taken correctly before patient transfer is commenced. Also, one staff member will be charged with ensuring and safeguarding the safe working environment within the MR scan room and is required to be present during all procedures. With these safety measures, no additional risk to the patient or operating team is expected. Most important potential benefits of intraoperative MR imaging during the RFA therapy are that per-procedural complications may be avoided by monitoring of temperatures near adjacent structures-at-risk as well as the ability to visualize the zone of effective treatment, which may hold predictive value for therapy response and patient prognosis.

## 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

Participation in PELICAN-trial and randomized for RFA-treatment

### Exclusion criteria

Contra-indications to undergo MR imaging

Impossibility to obtain informed consent

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Will not start

Enrollment: 20

Type: Anticipated

## Ethics review

Approved WMO

Date: 14-09-2017

Application type: First submission

Review commission: METC Amsterdam UMC

## 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	NL59767.018.17