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.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	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