Irreversible Electroporation for treatment of unresectable, locally advanced pancreatic cancer in the Leiden University Medical Centre: a phase I/II study.

Published: 29-10-2013
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Main objectiveTo investigate feasibility and safety of tumor ablation using IRE in patients with irresectable locally advanced pancreatic head carcinomas.Secondary objective(s)To investigate tumor downstaging efficacy, pain perception and hospital...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON40396

Source
ToetsingOnline

Brief title
IRE for unresectable pancreatic carcinoma the LUMC

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
carcinoma of the pancreas, pancreatic cancer

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: irreversible eletroporation, pancreas, unresectable

Outcome measures

Primary outcome

Safety and feasibility of the procedure

Secondary outcome

Tumor downstaging

VAS pain score

Hospital stay (days)

Immunological effects

Study description

Background summary

In the Netherlands neoadjuvant treatment for T3 or T4 tumors in patients free of distant metastasis is not a standard therapy. In the near future the PREOPANC trial will evaluate radiochemotherapy for borderline resectabel pancreatic head adenocarcinomas. Involvement of venous structures (beside complete thrombosis with portal hypertension) is not regard as an absolute contraindication for explorative laparotomy. Involvement of the superior mesenteric artery, celiac trunc or hepatic arteries is. Therefore a significant number of patients undergo an laparotomy without performing a pancreatic head resection. Mostly a biliary and gastrointestinal bypass is provided. Postoperatively chemotherapy is regarded as an adjunct to palliative treatment. When patients are postoperatively without clinical symptoms chemotherapy is not regarded as providing significant benefit.

Study objective

Main objective
To investigate feasibility and safety of tumor ablation using IRE in patients with irresectable locally advanced pancreatic head carcinomas.
Secondary objective(s)
To investigate tumor downstaging efficacy, pain perception and hospital stay in patients following IRE of irresectable locally advanced pancreatic head carcinomas .

Study design

Patients with pancreatic head carcinoma with involvement of venous structures to an extent that explorative laparotomy is warranted are eligible for IRE treatment when during laparotomy the tumor is proven to be irresectable. We anticipate to include 15 patients in 12 months.

Intervention

Irreversible electroporation (IRE) is a new ablation technique [Rubinsky 2007, Lee 2010]. By changing the electric potential across the cell membrane, the lipid bilayer is disrupted and becomes porous. With high voltages this process is irreversible leading by apoptosis to cell death. IRE is already effective at settings before heat is produced. Therefore it is defined as a non-thermal ablation technique were heatsink and direct thermal damage is not an issue. IRE is also shown to spare connective tissue architecture, leaving the architecture of bile ducts and other vital structures intact. This will allow ablations of tumors with close relation to vital structures.

Study burden and risks

Because of a possible advatage for survival, the minimal risk of IRE, as well as de CT-scans, is considerd acceptable. The CT-scans that are to be made, (5 for a 9month survival and a maximum of 9 for a 2 year survival) is not considered to be a risk, and is considered to be an acceptabel burden. The follow-up scans are stopped when there is progression of disease. The questionnaires and the venal punctions are not considered to be a risk, nor a burden.

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

Pre-operative inclusion criteria
• 18 years of age
• Tumor in the pancreas suspected for adenocarcinoma according to diagnostic set in the national guideline*
• Based on preoperative imaging the tumor is judged as resectable in the multidisciplinary meeting, but is also shown to have at least abutment of a venous vascular structure (portal vein, superior mesenteric vein) (see table 1 in Appendix A)
• Tumor size must be < 4 cm at the time of IRE treatment and must be measurable
• Karnofsky Performance Status score of >70% or ECOG of 0 to 1
• INR < 1.3
• ANC > 1.5x109/L
• Hemoglobin >6mmol/L
• Platelets > 100x109/L
• Renal function: eGFR >50ml/min
• Bilirubin level <250mmol/L
• Willing and able to comply with the protocol requirements
• Able to comprehend and have signed an Informed Consent Form (ICF) to participate in the study
* Suspected tumor in the pancreas on US and CT/MR, or, if necessary, followed by endoscopic ultrasound or ERCP with or without cytological and/or histological diagnosis

(www.oncoline.nl/pancreascarcinoom).;Per-operative inclusion criteria
• Unresectable during intraoperative ultra sound investigation after minimal surgical exploration:
• Extensive tumor growth around superior mesenteric vein and their side-branches (see table 2 in Appendix A).
• Involvement of arterial structures (see table 2 in Appendix A)
• Per-operative diagnosis confirmed by frozen section analysis

Exclusion criteria

• Contraindications for laparotomy or IRE
• Resectable at laparotomy
• Evidence of distant metastases (pre or per-operative) including cytological proven N2 metastases
• Stenosis >50% of Common Hepatic Artery and/or Celiac Trunc
• Inability to stop anticoagulant therapy for 7 days prior to and 7 days post treatment with the NanoKnife System
• Known history of contrast allergy that cannot be medically managed
• Women who are pregnant or currently breast feeding
• Women of child bearing potential who are not willing to use hormonal contraception or intrauterine device (IUD) during the study
• Have a cardiac pacemaker or defibrillator
• Have metal parts in the vicinity of lesions to be ablated at the time of treatment with the NanoKnife System
• Recent history of myocardial infarction (within the past 3 months)
• Patients with a history of Epilepsy
• Patients with a current history of clinically significant Cardiac Arrhythmia

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2013
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Irreversible electroporation
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-10-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	15-04-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21164
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45048.058.13
OMON	NL-OMON21164