Phase II study: Radiofrequency ablation of locally advanced pancreatic cancer

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Primary objective: to investigate the safety of RFA in non-metastasized, irresectable locally advanced pancreatic cancer.Secondary objectives: to determine VAS pain score, length of hospital stay, survival, progression free survival and CA19-9...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Exocrine pancreas conditions
Study type	Interventional

Summary

ID

NL-OMON37585

Source
ToetsingOnline

Brief title
Phase II: RFA of pancreatic cancer

Condition

- Exocrine pancreas conditions

Synonym
cancer of the pancreas, Pancreatic cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Irresectable, Locally advanced pancreatic cancer, Radiofrequency ablation, Therapy

Outcome measures

Primary outcome

Primary outcome parameter of the phase II study is safety.

The safety will be specified as the percentage of patients with complications directly related to RFA and requiring re-intervention (i.e. endoscopy, radiology, or surgery). This is also known as a complication of grade III or higher in the Clavien-Dindo classification (internationally accepted classification for surgical complications, see table 3) [20]. The complications directly related to RFA include pancreatitis, pancreatic fistula, perforation of the duodenum and thermal damage of the porto-mesenterial vein. Moreover all in-hospital complications or complications developed within 30 days after the RFA procedure will be evaluated according to the Clavien-Dindo classification.

The study will have a follow-up period of 3 months.

Secondary outcome

Secondary outcome parameters of the study are: VAS pain score, length hospital stay, survival, progression free survival and CA19-9 response.

Study description

Background summary

Pancreatic cancer is the most lethal abdominal malignancy and is the fourth leading cause of cancer-related death in the Western world. At time of diagnosis, 20% of patients present with a resectable tumour, 40% with non-metastasized irresectable locally advanced tumour and 40% with metastatic disease. The median survival of patients with locally advanced pancreatic cancer and metastatic disease is only 6 months. In patients with irresectable locally advanced pancreatic cancer chemotherapy with Gemcitabine is considered an accepted standard palliative treatment. However the survival benefit of Gemcitabine is minimal. Therefore, there is an urgent need for new and more effective therapies for patients with irresectable locally advanced disease.

Radiofrequency ablation (RFA) is a technique that has been demonstrated to be effective in the treatment of several irresectable tumours. RFA produces local tissue destruction through high frequency alternating current flowing from an electrode implanted directly into the tumour. The ions in the tissue attempt to follow the changing directions of the alternating current and cause frictional heating. Heating to over 60°C is known to have damaging effects on cell structure and physiology at many levels. A single RFA probe can be used as well as a combination of 2 or 3 probes depending on the size of the tumour. Promising results are reported in lung, bone, brain, kidney and prostate gland tumours. The last ten years several studies of RFA of pancreatic cancer have been performed as well. In several studies promising results of RFA of irresectable locally advanced pancreatic cancer are reported, among others by Girelli R. et al.

Study objective

Primary objective: to investigate the safety of RFA in non-metastasized, irresectable locally advanced pancreatic cancer.
Secondary objectives: to determine VAS pain score, length of hospital stay, survival, progression free survival and CA19-9 response.

Study design

The proposed study is a phase II non-randomized cohort study aimed at collecting safety data in 17 patients. Continuous safety monitoring is used.

Intervention

The investigational treatment of this study is radiofrequency ablation. Radiofrequency ablation of the pancreatic tumours will be produced through application of high frequency alternating current flowing from a probe with an electrode into the surrounding tissue. The ions in the tissue attempt to follow the changing directions of the alternating current and cause frictional heating. The tissue heats in the area that contacts the probe tip, and heat is then transferred conductively to more distant tissue. This leads to denaturing

(coagulation) of the cellular proteins and subsequent necrosis of the affected tissue volumes. The result is thermal injury of the cell structures and damage of the cell physiology at many levels. The coagulated necrotic tissue is recognized as such by the body and successively degraded by the body*s own mechanisms. In this way, it is possible to completely destroy a tumour where the indication is appropriate.

Study burden and risks

The prognosis of patients with irresectable locally advanced pancreatic cancer is very poor. The median survival of these patients is only 6 months. The risk of complications is 4-12% (see also E9). Considering the expected survival benefit of RFA (more than 1 year reported in literature), we consider the burden and risks of this treatment justified.

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

1. Patients with irresectable locally advanced pancreatic cancer found at laparotomy with histologic diagnosis before start of RFA
2. Patient considered eligible to undergo pancreatic surgery as assessed by the general criteria of the departments of anaesthesiology and surgery of the UMC Utrecht
3. Fully informed written consent given

Exclusion criteria

1. Patients younger than 18 years
2. Pregnancy
3. Patients with distant metastases
4. Portal vein thrombosis seen on CT preoperatively

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):	27-08-2012
Enrollment:	17
Type:	Actual

Medical products/devices used

Generic name:	Radiofrequency ablation

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-07-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
ClinicalTrials.gov	NCT01628458
CCMO	NL39333.041.11