Pancreatic Locally advanced Irresectable Cancer AblatioN (PELICAN trial)

Published: 24-12-2014
Last updated: 09-11-2024

The aim of the PELICAN trial is to investigate the survival benefit of RFA followed by chemotherapy as compared to standard palliative chemotherapy alone in patients with LAPC.

Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON56404

Source
ToetsingOnline

Brief title
PELICAN trial

Condition

- Gastrointestinal therapeutic procedures

Synonym
Locally advanced pancreatic cancer; non-resectabel pancreatic tumor

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W,KWF,Olympus

Intervention

Keyword: 'Locally advanced', 'Pancreatic cancer', 'Radiofrequency ablation' or 'RFA'

Outcome measures

Primary outcome

survival (in months)

Secondary outcome

Clinical: complications, toxicity of pre- and post-randomization chemotherapy,

VAS pain score

Pathophysiological: objective tumor reponse, progression free survival, CA 19-9

& CEA response, immunomodulation

Additional: quality of life, indirect and direct health costs

Study description

Background summary

Pancreatic cancer is the fifth leading cause of cancer-related death in the Netherlands. Each year around 900 patients in the Netherlands are diagnosed with *irresectable locally advanced pancreatic cancer* (LAPC) (i.e. without distant metastases). The median survival is only approximately 5-6 months and treatment options are limited, which moreover give only a minimal survival benefit. The current standard treatment in the Netherlands is palliative chemotherapy, which prolongs survival with only 2 to 3 months in most patients.

Radiofrequency ablation (RFA) is a new therapy for LAPC that may prolong survival. This technique involves the implantation of one or more electrodes directly into the tumor to inflict thermal damage using heat. RFA is widely used for cancer in other organs such as liver and prostate. Previous studies have demonstrated RFA to be feasible and safe in patients with LAPC and have shown an improvement of postoperative pain and survival rates of up to 12 months. These were however non-randomized studies with probable selection bias.

We have recently conducted two experimental studies and an observational phase II safety study in patients with LAPC and have confirmed RFA to be feasible and safe in these patients. In order to study the true effect of RFA in LAPC we designed the Dutch nationwide PELICAN trial.

Study objective

The aim of the PELICAN trial is to investigate the survival benefit of RFA followed by chemotherapy as compared to standard palliative chemotherapy alone in patients with LAPC.

Study design

A total of 212 patients with LAPC without distant metastases after 2 months of induction chemotherapy (i.e FOLFIRINOX or gemcitabine depending on WHO performance status and age), recruited in 16 centres of the Dutch Pancreatic Cancer Group, will be randomized for A) RFA followed chemotherapy or B) chemotherapy only. Both groups undergo a 1.5 years follow-up.

Intervention

Radiofrequency ablation, which is performed through a median laparotomy

Study burden and risks

The operation to perform RFA and hospitalization will be a big burden for the patient in the treatment group. Tumor tissue will also be taken from them during the RFA procedure as well as extra blood samples during hospitalization. The control group will only be treated with chemotherapy, which is standard care. All included patients will be checked at the outpatient clinic at 3, 6, 12 and 18 months after the start of treatment, during which patients have to fill in quality of life questionnaires and physical examination, blood tests and additional diagnostic tests are being performed if necessary.

Complications that may occur are bleeding (mainly during operation), pancreatitis, pancreatic fistula, ulcera of the duodenum or a portal vein thrombosis

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. Histologically or cytologically confirmed adenocarcinoma of the pancreas 2. Locally irresectable tumor (see Appendix 1 of the protocol for criteria) 3. Primary tumor 4. Stable disease or partial respons after 2 months of induction chemotherapy (according to RECIST) 5. Fit for chemotherapy as assessed by the medical oncologist plus: • Absolute neutrophil count >= 1.5 × 10^9/L • Platelet count >= 100 × 10^9/L • Renal function: creatinine clearance > 50 ml/min • Transaminases <= 3 x ULN 6. Fit for surgery assessed by the treating surgeon and anesthesiologist 7. RFA technical feasible (see Appendix 2 of the protocol for criteria) 8. Written informed consent 9. Age >= 18 years

Exclusion criteria

1. WHO performance status 3 or 4 2. Distant metastases on abdominal or thoracic CT scan* 3. Previous surgical, local ablative or radiotherapy for pancreatic cancer or chemotherapy which is inconsistent with the prescribed induction schedule according to protocol** 4. Stenosis of > 50% of the hepatic artery AND portal vein/ superior mesenteric vein 5. Second primary malignancy, except adequately treated non-melanoma skin cancer, in situ carcinoma of the cervix uteri or other malignancies treated at least 5 years previously without signs of recurrence. 6. Pregnancy * Positive or suspicious regional lymph node metastases are not a reason for exclusion ** Surgical exploration is not a contra-indication for inclusion kan zij

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-04-2015
Enrollment:	174
Type:	Actual

Medical products/devices used

Generic name:	radiofrequency ablation
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	25-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	06-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.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

No registrations found.

In other registers

Register	ID
CCMO	NL50467.018.14