Cone-beam CT guided Stereotactic Radiation Therapy for Locally Advanced and Locally Recurrent Pancreatic Cancer

Published: 15-05-2013
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To determine safety and technical feasibility of stereotactic radiotherapy for locally advanced and locally recurrent pancreatic carcinoma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON43956

Source
ToetsingOnline

Brief title
SBRT for pancreatic cancer

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
pancreatic cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cone-beam CT, locally advanced or locally recurrent pancreatic carcinoma, SBRT, stereotactic

Outcome measures

Primary outcome

The main study endpoint will be safety of the procedure, expressed in

proportion of patients experiencing treatment-induced toxicity grade 3 or more

according to the CTC-AE 4.0 due to the complete procedure within 90 days of the

last irradiation.

Secondary outcome

Other study parameters will be technical feasibility, treatment response,

quality of life, overall survival, progression free survival, and rate of

possible secondary resections.

Study description

Background summary

Pancreatic cancer has a very poor survival, due to late diagnosis and lack of sufficient treatment options for locally advanced tumors and metastasized patients. High dose radiotherapy with small margins seems feasible with current technical possibilities, e.g. by fiducial guided stereotactic radiotherapy. In this study, we want to evaluate safety and technical feasibility for cone beam CT guided stereotactic radiotherapy for locally advanced and locally recurrent pancreatic carcinoma.

Study objective

To determine safety and technical feasibility of stereotactic radiotherapy for locally advanced and locally recurrent pancreatic carcinoma.

Study design

Pilotstudy to determine safety and feasibility.

Intervention

Pre-treatment, (recurrent) pancreatic cancer has to be pathology proven. Patients will undergo a contrast-enhanced CT scan, a contrast-enhanced MRI scan, endoscopic fiducial placement, and patients will get a custom-made individual corset. Baseline toxicity and quality of life will be assessed. Radiotherapy will be delivered in three fractions on an outpatient basis. After treatment, follow-up will be at 1, 3, 6, and 12 months. Toxicity and quality of life will be assessed during these outpatient department visits. A CT scan and an MRI scan will be performed 3 months after treatment to assess treatment response.

Study burden and risks

Increased severe toxicity may occur due to the intervention, but treatment related toxicity should be limited due to strict dose constraints to the organs at risk (e.g. duodenum, stomach). Potential benefits may be pain relief, due to local control of the tumor, and a prolonged survival.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Pancreatic cancer:
- Primary unresectable pancreatic tumors according to Dutch Pancreatic Cancer Group; or
- Medically inoperable patients with pancreatic cancer; or
- Isolated locally recurrent pancreatic cancer.
* *18 years.
* Written informed consent.

Exclusion criteria

* Evidence of distant metastasis.
* WHO performance status 3-4.
* Expected life span <3 months.
* Exclusion criteria for contrast enhanced MRI and/or CT scan, following the protocol of the department of radiology UMCU.

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):	10-07-2013

Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	15-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-07-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-10-2016
Application type:	Amendment
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	NCT01898741
CCMO	NL42053.041.12