

Image-guided radiochemotherapy in patients with pancreatic cancer using gold markers placed during endoscopic ultrasound.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23455

Source

NTR

Health condition

Patients with (borderline) resectable or locally advanced pancreatic cancer with an indication for radiochemotherapy

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam

Source(s) of monetary or material Support: Academic Medical Center Amsterdam

Intervention

Outcome measures

Primary outcome

Clinical success: defined as the ability to use the fiducials in applying image-guided radiotherapy

Secondary outcome

- Technical success: defined as the ability to implant at least three fiducials in the tumour area;
- Technical difficulty: cumbersome loading or unloading of a fiducial. After the procedure the endosonographers will value the ease of placement by filling out a scale of 1-5, to evaluate the ease of placement of the fiducials. A value of ≥ 4 is considered difficult;
- Safety: the procedure is considered safe if the maximum rate of SAEs related to the EUS-guided fiducial placement does not exceed 5%, based on the number of major complications following EUS-guided fine needle aspiration (EUS-FNA) of solid pancreatic masses (2.5% (95% CI 0.7-6.3%);20,21
- Migration: change in interfiducial distance. The coordinates of the fiducials are determined by manually selecting the centre of each fiducial on the reference scan. From these 3D coordinates, the interfiducial distances are calculated;
- Complete migration: non-visualization of a fiducial on the reference scan, or the disappearance of a previously visualized fiducial on any of the following CBCT scans.

Study description

Study objective

EUS-guided fiducial placement in pancreatic tumors is a technically successful and safe procedure. After placement fiducials can be successfully used for highly-accurate delivery of image-guided radiotherapy.

Study design

Follow-up call/visit for complications: 48-72 hours, 7 days and 30 days post-procedure

Intervention

EUS-guided placement of fiducials in a pancreatic tumor

Contacts

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Eligibility criteria

Inclusion criteria

- Patient over 17 years old;
- Indication for radio(chemo)therapy for pancreatic carcinoma;
- WHO performance status of 0-2;
- Verbal informed consent.

Exclusion criteria

- Altered anatomy of the pancreatic region;
- Any contraindication for EUS-guided fiducial placement.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	08-04-2014
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion	
Date:	04-04-2014
Application type:	First submission

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
NTR-new	NL4252
NTR-old	NTR4490
Other	METC AMC : W14_021

Study results