

# Feasibility of breath-hold techniques in irradiation of pancreatic cancer

Published: 18-03-2014

Last updated: 20-04-2024

The measurement of pancreatic tumour motion during end expiratory and end inspiratory breath hold during the preparatory CTscan and three radiation fractions and comparing this with the tumour motion during free breathing. The assessment of the...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal neoplasms malignant and unspecified
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON40629

### Source

ToetsingOnline

### Brief title

BREATHPANC2013

### Condition

- Gastrointestinal neoplasms malignant and unspecified

### Synonym

pancreatic cancer

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Eén van de studietoelagen (ELS) is promovendus op een gerelateerd KWF project

## Intervention

**Keyword:** breath hold technique, irradiation, pancreatic cancer

## Outcome measures

### Primary outcome

tumour motion during the preparatory CT scan and during three radiation fractions under breathhold conditions compared to the tumour motion under free breathing conditions.

Practical feasibility of applying a breathhold technique in patients with pancreatic cancer.

### Secondary outcome

Calculation of the impact of the above indicated measurements on the safety margin for irradiation of pancreatic cancer

## Study description

### Background summary

During irradiation for pancreatic cancer a safety margin has to be taken into account for tumour motion due to breathing. Endosonographically implanted gold fiducials have recently been introduced to visualize the tumour on CT scans and during radiotherapy on cone beam CT scans, to enhance the accuracy of radiation. Thanks to these fiducials we have been able to measure that intrafractional tumour motion may be in the order of 1 cm, particularly in craniocaudal direction.

We hope to diminish this intrafractional tumour motion by applying breathhold techniques, giving radiation while the patient holds his or her breath during inspiration or expiration. Whether this is useful in pancreatic cancer is not known, since it is possible that the intrafraction tumour motion is partly dependent upon other factors than breathing.

### Study objective

The measurement of pancreatic tumour motion during end expiratory and end inspiratory breath hold during the preparatory CTscan and three radiation fractions and comparing this with the tumour motion during free breathing.

The assessment of the feasibility of a breath hold technique for irradiation of pancreatic cancer.

## **Study design**

In 10 patients being irradiated for their (borderline) resectable pancreatic cancer who give informed consent for participation in this study, The tumour motion will be measured in breath hold conditions during the preparatory CT scan and during three radiotherapy fractions and will be compared to the tumour motion in free breathing conditions. During the preparatory phase this will be done taking extra CT-scans during breath hold in inspiration and expiration. During the three radiotherapy fractions extra cone beam CT scans in breath hold conditions and fluoroscopy in breath hold conditions will be performed.

Based on these measurements, the potential impact of a breath hold technique on the safety margins for irradiation of pancreatic cancer will be calculated.

## **Study burden and risks**

Participation to this study will mean an extra time investment for the patient of about an hour in the preparatory phase and three times a quarter of an hour during the radiation course. There is an extra radiation burden of 390-675 milliSievert, comprising less than 2% of the total therapeutic radiation dose that is prescribed.

If, indeed, the safety margins can be diminished by applying a breath hold technique for radiation of pancreatic cancer, this may lead to less toxicity and hence improvement of the therapeutic window for radiochemotherapy.

## **Contacts**

### **Public**

Academisch Medisch Centrum

Meibergdreef 9  
Amsterdam 1105 AZ  
NL

### **Scientific**

Academisch Medisch Centrum

Meibergdreef 9  
Amsterdam 1105 AZ  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- \* Patients with pancreatic cancer, with locally advanced or (borderline) resectable status, who are treated with radio(chemo)therapy;
- \* WHO performance status of 0-2;
- \* Written informed consent.

### Exclusion criteria

- \* Inability to undergo the additional treatment planning CT scan and fluoroscopy;
- \* Serious lung condition precluding breath-hold.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2014
Enrollment:	10
Type:	Actual

## Ethics review

Approved WMO	
Date:	18-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

## 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	NL47655.018.14