A study of respiratory waveforms derived using up to three motion monitoring systems in 4D radiotherapy planning and delivery

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To compare respiratory waveforms generated using reflective markers located on the upper abdominal wall (the currently used Varian RPM system) with either magnetic sensors, belt sensors or both placed on the chest wall and/or upper abdomen. The...

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON30296

Source ToetsingOnline

Brief title New respiratory motion monitors for radiotherapy

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Respiratory tract neoplasms

Synonym lung cancer; upper abdominal cancer

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: 4D radiotherapy, radiotherapy, respiration measurement, respiratory motion

Outcome measures

Primary outcome

To compare respiratory waveforms generated using the standard method with two

new measurement systems. The generated waveforms will also be correlated with

tumour position and movement.

Secondary outcome

1. Determine if gating parameters derived from either magnetic or belt sensors

can substitute for data from the presently used RPM system.

2. Develop improved strategies for delivering respiration-gated radiotherapy

(RGRT) using multiple respiratory signals

Study description

Background summary

In 4D radiotherapy, patients undergo planning and/or delivery based upon respiratory waveforms. The currently used technology to measure respiratory waveforms (the RPM system) will be incompatible with the future PET-CT, implying that at least two different respiration monitoring systems will be used for 4D treatments at VUmc. These systems must be mutually compatible in order to insure accuracy of treatment delivery.

Study objective

To compare respiratory waveforms generated using reflective markers located on the upper abdominal wall (the currently used Varian RPM system) with either magnetic sensors, belt sensors or both placed on the chest wall and/or upper abdomen. The generated waveforms will be correlated with tumour position and movement.

Study design

Thirty patients will undergo standard 4DCT planning scans using both devices (belt and magnetic sensors) in addition to the standard RPM device. If a patient cannot tolerate the use of both systems, additional patients will be recruited in order to generate full numbers.

When patients undergo subsequent radiotherapy, monitoring of respiratory waveform will be performed using at least 1 of the 2 systems (belt and magnetic sensors) during treatment delivery. A minimum of 30 patients will be included. Total = 30-50 patients

Study burden and risks

None, except the relativelty short time needed to apply the measurement devices. No extra CT-scans will be performed, respiratory waveforms will be collected during the standard radiotherapy planning 4DCT scan. The studies are exploratory and no intervention is planned on the basis of the additional recordings. All measurement methods are non-invasive.

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

Patients undergoing a respiration correlated (4D) CT scan as part of their standard radiotherapy treatment preparation.

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	50
Туре:	Anticipated

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Ethics review

Approved WMO Application type: Review commission:

First submission 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 CCMO ID NL14350.029.06