Reduction of organ motion during radiotherapy by non-invasive mechanical ventilation supported breathing control.

No registrations found.

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

Summary

ID

NL-OMON24117

Source
NTR

Brief title
BreaCoRTH

Health condition

Cancer (breast cancer, mediastinal tumours, lung cancer, liver tumours and pancreatic cancer). (Note: we will also include healthy volunteers).

Sponsors and support

Primary sponsor: Amsterdam UMC - Radiotherapy
Source(s) of monetary or material Support: Dutch Cancer Society (KWF project number 12900)

Intervention

Outcome measures

Primary outcome

The main endpoint is the feasibility to achieve regularized breathing, compensated prolonged

breath-holding and high frequency ventilation in healthy volunteers and cancer patients to quantify reduced dose to organs at risk as compared to DIBH and FB.

Secondary outcome

The secondary endpoints are reached if the practical advantages and limitations of the novel breathing control strategies for routinely radiotherapy delivery in cancer patients have been identified, i.e.:
• subjects' comfort with the different breathing control strategies has been assessed using a short questionnaire;
• cost effectiveness in terms of time investment has been analysed.

Study description

Background summary

Radiotherapy with or without surgery and chemotherapy is an important treatment for many thoracic and abdominal cancers, including breast and lung cancer, mediastinal tumours, liver tumours, and pancreatic cancer. To minimize the risk of acute and late radiation-associated toxicity, irradiated tissue volumes should be kept as small as possible. However, large and irregular breathing amplitudes during free breathing require large safety margins. To account for respiratory motion and daily anatomical variations, treatment volumes are expanded beyond the tumour to ensure complete target volume irradiation. Consequently, normal tissues surrounding the tumour may be exposed to high radiation doses.
Current clinical practice for a range of thoracic and abdominal cancer patients reduces respiratory motion during radiotherapy while patients perform multiple (~10) and short (~20-35 secs) deep-inspiration breath-holdsfrom room air. The effectiveness depends on patients' compliance and their response to feedback. Besides, tumour and organ position can vary considerably between multiple short breath-holds, and residual motion occurs. Safety margins are still required.
Non-invasive mechanical ventilation supported regularized breathing can reduce respiratory motion compared to free breathing. Furthermore, combining non-invasive mechanical hyperventilation (causing safe hypocapnia) with pre-oxygenation enables single prolonged breath-holding (≥5 mins). Our pilot study (METC NL64693.018.18) unveiled a residual diaphragm motion during proloonged breath-holding.
In this study, we aim to establish compensated prolonged breath-holding by mechanical re-inflation of oxygen during breath-holding to compensate for gradual lung deflation. High frequency ventilation is a strategy where the subject needs not take any breaths for a prolonged period (~10 mins), since the high frequency oscillation of gasses ensures adequate gas exchange.

Study objective

Respiratory motion will be maximally reduced during compensated prolonged breath-holding

where gradual lung deflation is abolished by mechanical re-inflation of oxygen, and high frequency ventilation is expected to be equally effective. Regularized breathing with lower frequencies is the second best solution to reduce organ motion.

Study design

The feasibility to achieve mechanical ventilation supported breathing control strategies in heatlhy volunteers and cancer patients will be demonstrated at four time points:
1. Training session 1
2. Training session 2
3. MRI session 1
4. MRI session 2
At the same time points, subject's comfort with each of the breathing control strategies will be assessed.
The effect of the breathing control strategies on (residual) organ motion in healthy volunteers will be quantified on MR images.
The effect of the breathing control strategies in cancer patients will be quantified in terms of reduced dose to OARs by comparing radiation treatment plans.

Intervention

Subjects will be trained in approximately two sessions to feel safe and comfortable while being mechanically ventilated via a face mask and viral filter. Step by step they learn to to achieve safely compensated prolonged breath-holds and to undergo high frquency ventilation. In two subsequent sessions, MRIs will be acquired during these procedures.

Contacts

Public
Amsterdam UMC, location Academic Medical Center
Irma W.E.M. van Dijk

+31 (0) 5666823
Scientific
Amsterdam UMC, location Academic Medical Center
Irma W.E.M. van Dijk

+31 (0) 5666823

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, subjects must meet all of the following criteria:
• age >18 years
• adequate communication and understanding skills of Dutch language
• referred to or undergoing radiotherapy with DIBH at the department of radiation oncology of the Amsterdam UMC
• condition: KPS >70 or WHO PS max 1 (see 4.3 Exclusion criteria)
• signed informed consent (IC)

Exclusion criteria

Any potential subject with (a history of) any of the following conditions will be excluded from participation in this study:
• asthma controlled by medication
• moderately to severely impaired lung function (FEV1 <30% of predicted)
• resting PetCO2 >50 mmHg
• manifest cardiac failure
• epilepsy
• hypertension uncontrolled by medication
• brain disease, and/or anomalies of the brain's vasculature or previous TIA/CVA
• morbid obesity, i.e. BMI >40 kg/m2
• pneumothorax
• renal failure
• claustrophobia
• current pregnancy
• any 3T MRI contra-indications as stated by the AMC MR safety committee
Furthermore, patients will be excluded if they have:
• any tumour that is not clinically definable on planning CT due to e.g. surrounding consolidation or atelectasis
• a tumour located within 2cm radius of main airways and proximal bronchial tree

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-10-2021
Enrollment:	90
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
NA

Ethics review

Positive opinion

Date:	29-03-2021
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	NL9841

Register	ID
Other	AMC-METC : METC NL77351.018.21

Study results

Summary results
NA