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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

### Samenvatting

#### ID

NL-OMON24117

Bron NTR

# Verkorte titel

BreaCoRTH

#### Aandoening

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

#### Ondersteuning

**Primaire sponsor:** Amsterdam UMC - Radiotherapy **Overige ondersteuning:** Dutch Cancer Society (KWF project number 12900)

#### **Onderzoeksproduct en/of interventie**

#### Uitkomstmaten

#### Primaire uitkomstmaten

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.

# **Toelichting onderzoek**

#### Achtergrond van het onderzoek

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 ( $\sim$ 10) and short ( $\sim$ 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 ( $\geq$ 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 reinflation 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 ( $\sim$ 10 mins), since the high frequency oscillation of gasses ensures adequate gas exchange.

#### Doel van het onderzoek

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.

#### Onderzoeksopzet

The feasibility to achieve mechanical ventilation supported breathing control strategies in heatly 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.

#### **Onderzoeksproduct en/of interventie**

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.

### Contactpersonen

#### **Publiek**

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#### Wetenschappelijk

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### **Deelname eisen**

#### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

# Onderzoeksopzet

### Opzet

Туре:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

#### Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	17-10-2021
Aantal proefpersonen:	90
Туре:	Verwachte startdatum

#### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

**Toelichting** NA

## **Ethische beoordeling**

Positief advies	
Datum:	29-03-2021
Soort:	Eerste indiening

# Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

#### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

#### In overige registers

**Register** NTR-new Ander register ID NL9841 AMC-METC : METC NL77351.018.21

# Resultaten

#### Samenvatting resultaten

NA