Utrecht Breathing Regulation Effectiveness for Abdominal and THoracic External-beam Radiotherapy (U-BREATHER)

Published: 12-07-2023
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To assess the feasibility of participants positioned in an MRI scanner to regulate their breathing based on biofeedback

Ethical review	Approved WMO
Status	Completed
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON53578

Source
ToetsingOnline

Brief title
U-BREATHER

Condition

- Miscellaneous and site unspecified neoplasms benign
- Respiratory tract neoplasms

Synonym
breathing regulation, radiotherapy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W,Elekta Solutions

Intervention

Keyword: Breathing regulation, Gating, MRI, MR-Linac

Outcome measures

Primary outcome

Percentage of time the breathing instructions are followed correctly as

instructed.

Secondary outcome

- Response time to a new instruction on the GUI concept.

- The number of subject who prematurely stop the MRI.

- The duration of the subject-determined breath hold (SDBH)

- System Usability Scale (SUS)

Study description

Background summary

Respiratory motion is an important source of targeting uncertainty that affects abdominal and thoracic external-beam radiotherapy deliveries. Treatment simulation imaging and treatment deliveries can benefit from active breathing regulation techniques which ensure that patients are irradiated in a favourable anatomy.

Biofeedback systems are needed to ensure optimal compliance with breathing instructions.

Before clinical implementation in radiotherapy workflows, the technical feasibility of different biofeedback system prototypes needs to be established.

Study objective

To assess the feasibility of participants positioned in an MRI scanner to

regulate their breathing based on biofeedback

Study design

A mono-center feasibility study at the UMCU with a cross-sectional design

Intervention

Participants will be asked to follow breathing instructions according to user interface concepts explored during research-only MR imaging sessions

Study burden and risks

No risk or treatment-related benefit is expected. Participants are asked to participate in a single MR imaging session and fill out questionnaires. Imposed breathing instructions, in addition to a small risk of hyperventilating, have a real risk of triggering mild anxiety.

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

- >= 18 years.
- Capable to provide informed consent.
- Healthy volunteers
or
- Patients that receive treatment on a tumor-lesion in the thorax or upper abdomen.

Exclusion criteria

- Contraindication for MRI scanning as listed in screening form.
- Refusal of subjects to be informed of chance findings possibly relevant to their health
- In case study participation would interfere with regular treatment.
- Visual impairment in treatment position including:
o Visual impairment that cannot be corrected through use of MR Safe contact lenses of
MR configurable MR Safe prescription glasses.
o Visual impairment due to treatment position or treatment position devices
- Severe obstructive or restrictive lung disease: If a participant suffers from severe obstructive or
restrictive lung disease, or unaware of the severity, a pulmonary specialist will be consulted to
determine whether participation is safe.
- Pregnancy

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	29-01-2024
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	Biofeedback
Registration:	No

Ethics review

Approved WMO Date:	12-07-2023
Application type:	First submission
Review commission:	METC NedMec

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	NL82354.041.23