Breathing guidance effectiveness for abdominal and thoracic MR imaging UMC Utrecht

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To assess the impact of using breathing instructions while performing motion-compensated MR imaging of lesions in the thorax or abdomen aimed at radiotherapy treatment planning as compared to motion-compensated scans without instructions and free-...

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON57328

Source
ToetsingOnline

Brief title
GUIDING-U

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
Breathing regulation, MRI

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Philips,Rijksdienst voor ondernemend

Nederland

Intervention

Keyword: Breathing regulation, MRI

Outcome measures

Primary outcome

Primary outcome: Scan time or scan completeness.

Secondary outcome

Patient reported experience, Image quality, Delineation consistency, Compliance

to breathing instructions.

Study description

Background summary

To increase precision in radiotherapy treatment of moving organs, use of motion-compensated scans instead of non-compensated scans is crucial. However, these motion-compensated free-breathing MRI scans currently suffer from long and unpredictable scan times and/or variable image quality. Causes for this are irregular breathing patterns and/or the breathing frequency itself. We anticipate that scan time and scan quality can be improved by actively guiding patients to breathe in a certain pattern. Furthermore, active breathing guidance might also have a positive effect on patient experience. Respiratory instructions (with Breathing Guidance, non-CE software) are supplied to the participants by the conventional audiovisual system, which is incorporated in the MRI room.

Study objective

To assess the impact of using breathing instructions while performing motion-compensated MR imaging of lesions in the thorax or abdomen aimed at radiotherapy treatment planning as compared to motion-compensated scans without instructions and free-breathing scans without motion compensation and without instruction.

Study design

A mono-center cross-over study
Study population:
12 healthy volunteers and 16 patients with a lesion in the thorax or abdomen, who are referred to the Radiotherapy department for radiotherapy. Patients and volunteers should be >18 years old and fluent in Dutch. Patients and volunteers who have contra-indications for MRI scans will be excluded from study participation.

Intervention

Participants will be asked to follow breathing instructions according to a user interface concept 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.

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.
• Dutch speaking
• Healthy volunteers, or
• Patients that (will) receive radiotherapy treatment on a lesion in the thorax or 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:
o Visual impairment of -3 diopter or worse (see IMDD) which cannot be corrected through use of contact lenses of MR configurable MR Safe prescription glasses.
o Any other reason that restricts viewing of the in-room display by the participant (e.g. position of the mirror cannot be changed sufficiently to allow a view on the screen by the volunteer).
• Auditory impairment:
o Participants that cannot sufficiently hear the audio instructions and questions over the MRI head phones.
• 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
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	28
Type:	Anticipated

Medical products/devices used

Generic name:	Breathing Guidance
Registration:	No

Ethics review

Approved WMO

Date:	21-02-2025
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	NL87853.041.24