Quantification of bowel motility in gynecological cancer patients during radiotherapy using MRI.

Published: 24-05-2018
Last updated: 11-04-2024

* The primary objective is: the quantification of bowel motility in gynecological cancer patients undergoing radiotherapy using MRI. * The Secondary objectives are: - assessment of bowel motility variation within a patient during their treatment...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON48630

Source
ToetsingOnline

Brief title
Bowel motility during radiotherapy

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Bowel motility

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bowel motility, Gynecological cancer, MRI, radiotherapy

Outcome measures

Primary outcome

The primary study parameter of the study is to quantify bowel motility in three orthogonal directions in gynecological cancer patients treated with definitive radiotherapy using MRI.

Secondary outcome

The secondary study parameters/endpoints are :

- assessment of bowel motility variation within a patient during their treatment course.
- assessment of bowel motility variation between patients with a focus on changes of bowel motility associated with major abdominal surgery.

Study description

Background summary

To reduce the risk of bowel toxicity in gynecological malignancies patients undergoing curative radiotherapy, irradiation of organs at risk (OARs) (i.e. bowel and bladder) should be minimized. Gynecological malignancies are standardly irradiated with high radiation doses, typically delivered by external beam radiotherapy (EBRT) sessions followed by one or two brachytherapy (BT) sessions. During the treatment course, patients undergo three or four magnetic resonance imaging (MRI) scans, which are used for treatment planning. Based on the delineated tumor and OARs, radiation doses are calculated. However, variation in bowel position due to bowel motility can result in unpredictable dose distributions with the risk of exceeding the planned doses. Deviating from the planned dose may lead to increased risk of severe acute and late/chronic bowel toxicity. Therefore, bowel motility during radiation should

ideally be taken in account and integrated in the treatment planning. However, until to date, methods for assessing bowel motility during radiotherapy treatment are non-existing.

In this pilot study, we aim to quantify bowel motility in gynecological cancer patients undergoing radiotherapy using MRI. Furthermore, to gain more understanding about bowel motility in this patient group, we would also like to assess variation in bowel motility induced by several factors (for example radiation, patient preparation for brachytherapy and previous major abdominal surgery). MRI provides 3D images with good quality for accurate motility assessment. In addition, MRI is a non-invasive modality with no radiation burden making it the best tool for this pilot study.

Study objective

* The primary objective is:
the quantification of bowel motility in gynecological cancer patients undergoing radiotherapy using MRI.

* The Secondary objectives are:
- assessment of bowel motility variation within a patient during their treatment course.
- assessment of bowel motility variation between patients with a focus on changes of bowel motility associated with major abdominal surgery.

Study design

This pilot study will be conducted in ten gynecological cancer patients undergoing definitive radiotherapy with curative intent. In the standard care, patients undergo 3 to 4 MRI scans at different time points (prior to and during radiotherapy). To quantify bowel motility, an extra MRI sequence (10 min) will be added to the standard MRI scans (45 min). From the obtained MRI scans, bowel motility will be quantified. Bowel motility will be expressed as bowel displacement in three orthogonal directions. The motility between the MRI scans will be compared within and between patient in order to assess the effect of radiation, patient preparation and abdominal surgery in the past on bowel motility.

Study burden and risks

The additional motility MRI sequence will be added to each standard MRI scans (45 min, three to four times). Each motility scan will take about 10 minutes. The burden during the entire treatment course will be thus extra 30-40 minutes scan time over a period of seven to eight weeks. Since MRI is not invasive with no radiation burden, patients are not susceptible to radiation hazards.

However, being in a MRI for about an hour can be uncomfortable, therefore patients are free to halt the procedure and withdraw from the motility MRI scan at any time. Patients will not benefit from participation in this study.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100 DD
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100 DD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* age >18 years
* Treatment plan: Definitive radiotherapy with curative intent ± chemotherapy or hyperthermia
* Tumor type and stage:
- Cervical carcinoma (FIGO IB-IVA).
- Vaginal carcinoma (FIGO I-IVA).
- Isolated vaginal recurrence of endometrial carcinoma.

* Written informed consent

Exclusion criteria

* Claustrophobia
* Any 3T MRI contra-indications stated by the AMC MRI safety committee (See protocol appendix A)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2018
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	24-05-2018
Application type:	First submission
Review commission:	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	ID
CCMO	NL65554.018.18