The MOMENTUM Study - The Multiple OutcoMe EvaluatioN of radiation Therapy Using the MR-Linac

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON52371

Source
ToetsingOnline

Brief title
MOMENTUM

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Elekta Ltd

Intervention

Keyword: Cancer, MRI, MR-Linac, Radiotherapy

Outcome measures

Primary outcome

MOMENTUM will collect technical and clinical patient data. The technical patient data is defined as data generated by (the use of) the MR-Linac and will include data collection during scans performed during routine care as well as research MRIs. Clinical data will be categorized into six classes: demographic, disease characteristics, treatment classifiers, toxicity outcomes, cancer control outcomes and PROs.

Secondary outcome

NA

Study description

Background summary

Radiation therapy has become indispensable in cancer treatment. However, it is associated with severe side effects. Innovation in radiation therapy has resulted in the development of MR-guided radiation therapy (MRGRT) which allows high precision radiotherapy under real time MR visualization. High precision MRGRT has the potential of dose escalation and margin reduction and may potentially lead to higher cure rates and less toxicity. MRGRT can be delivered by the MRI guided Linear Accelerator (MR-Linac) which integrates a state-of-the-art linear accelerator, 1.5T diagnostic quality MRI and an online adaptive workflow.

Study objective

The Multi-OutcoMe EvaluatioN of radiation Therapy Using the MR-Linac Study (MOMENTUM) aims to accelerate the technical and clinical development of Anatomic and Functional MRGRT and facilitate the evidence-based introduction of the MR-Linac into clinical practice. In MOMENTUM, technical and clinical data

are gathered in order to optimize software, evaluate treatment outcomes, toxicities and progression free, disease free, and overall survival per disease site, and create a repository of anatomical and functional MR sequences to develop new features. Furthermore, the cohort will provide the logistics for future intervention studies according to the TwiCs design. This enables efficient hypothesis testing with a comparable reference population from the same cohort. The MOMENTUM cohort study is expected to enable optimal radiation treatment approach to improve patients* survival, local, and regional tumor control and quality of life.

Study design

A multi-institutional, international observational cohort study with the option for intervention studies possibly according to the TwiCs design.

Study burden and risks

No benefits are expected for the participants.
No risks are known for patients undergoing research MRI, since they will be screened according to the MRI safety criteria. The risk of breach of privacy and confidentiality will be managed by strict adherence to data safety and security procedures.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Patient is to undergo or has completed imaging or is eligable for treatment procedures on an MR-Linac;
- Patient provides written, informed consent;
- Patient is 18 years old or older.

Exclusion criteria

MRI exclusion criteria, including
- MRI contraindications as per usual clinical care, such as (possible) pregnancy, claustrophobia and metal or electronic implants not compatible with MRI;

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	13-02-2019
Enrollment:	10000
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	19-12-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	23-04-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-03-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-07-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-12-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-07-2023

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-01-2024
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-10-2024
Application type:	Amendment
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	NL66650.041.18