Evaluation of a Cone-beam CT scanner for Image Guided Radiotherapy.

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The main objective of this study is to evaluate the image quality of a new cone-beam CT imaging system that will be used to acquire images of a wide selection of anatomical locations in patients receiving radiotherapy for cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON55950

Source
ToetsingOnline

Brief title
CONFIGURE

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
cancer, Malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Varian, a Siemens Healthineers Company
Source(s) of monetary or material Support: Varian Medical Systems

Intervention

Keyword: Cancer treatment, Cone-beam CT, Radiotherapy

Outcome measures

Primary outcome

Qualitative and quantitative comparison of the image quality of the novel

cone-beam CT imaging system to standard cone-beam CT imaging and conventional

fan beam CT imaging used for radiotherapy planning purposes.

Secondary outcome

Evaluation of the suitability of the novel CBCT images for radiation treatment

planning and dose calculation.

Study description

Background summary

A novel cone-beam computerized tomography (CT) imaging system has been developed for image-guided radiotherapy. This new system can acquire cone-beam CT (CBCT) images faster than previous systems. Furthermore, the new system has demonstrated increased image quality, resolution and Hounsfield Unit (HU) accuracy in phantom images compared to previous cone-beam CT systems. This CBCT system opens new possibilities for use of CBCT images in various radiotherapy tasks for which previous CBCT images were not optimal. Specifically, the use of CBCT images for delineation of anatomical structures, radiotherapy treatment planning and radiation treatment dose calculation is limited with current on-board imaging technology. The improved image quality of the new system will be evaluated in a clinical setting with respect to its suitability for tumour and organ delineation, image-guided radiotherapy and radiation dosimetry.

Study objective

The main objective of this study is to evaluate the image quality of a new cone-beam CT imaging system that will be used to acquire images of a wide selection of anatomical locations in patients receiving radiotherapy for cancer.

Study design

Single arm, non-randomized prospective study.

Study burden and risks

There is no direct benefit expected for the individual patients who participate in this study. Additional imaging is performed on the novel cone-beam CT imaging device using x-rays. Additional radiation exposure resulting from the two additional CBCT images acquired for this study is a small fraction (<0.1%) of the radiation received during a subject*s standard radiotherapy treatment. Collected data will not be used for clinical decision making. If the novel CBCT images provide new information that may lead to improved treatment, the findings will be communicated to the treating physician but will require verification using standard imaging procedures.

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

The patient will be treated with external beam photon radiotherapy at MAASTRO for head-and-neck cancer, stage I lung cancer, stage II-IV lung cancer, breast cancer, or tumours in the abdominal or pelvic region.

Age >= 18 years

Ability to understand the requirements of the study and to give written informed consent, as determined by the treating physician

Provision of written informed consent

Exclusion criteria

Patient is pregnant

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2023
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Halcyon - Cone beam CT scanner
Registration:	No

Ethics review

Approved WMO Date:	14-03-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT05524454
CCMO	NL81936.068.22