Feasibility of CBCT-guided online adaptive radiotherapy

Published: 07-07-2023
Last updated: 07-04-2024

The primary objective is to test the feasibility of daily adaptive radiotherapy plan based on the cone beam CT. The expectance is that this new technique will make the radiotherapy more precise which results in less side effects or patient could...

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

Summary

ID

NL-OMON53283

Source
ToetsingOnline

Brief title
FASCINATE

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
bladder, cervix, lung or head and neck cancer, Prostate

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: vanuit eigen RT-afdeling AVL

Intervention

Keyword: Cone-beam computed tomograph (CBCT), Feasibility, Online adaptive, radiotherapy

Outcome measures

Primary outcome

The feasibility of online CBCT-guided adaptive radiation therapy on a standard

Elekta Linac.

Secondary outcome

Treatment associated >= grade 3 acute toxicity according to the NCI Common

Terminology Criteria of Adverse Events (CTCAE version 4.03).

Study description

Background summary

The radiotherapy plan is generally based on a single Computed Tomography (CT) scan obtained before the start of the treatment. However, the tumor and surrounding tissues change during the treatment schedule in position, shape and size. To make sure the tumor is treated, safety margins are accounted for. This however results in that more healthy tissue will also receive radiotherapy which will lead to more side effects.

On the Elektra linac a cone beam CT is connected. This cone beam CT is currently used for positioning the radiation plan towards the patient. However, the radiation would be precizer if the radiotherapy plan would be adjusted based on the cone beam CT.

Study objective

The primary objective is to test the feasibility of daily adaptive radiotherapy plan based on the cone beam CT.

The expectance is that this new technique will make the radiotherapy more precise which results in less side effects or patient could receive a higher radiation dose.

Study design

Prospective, non-randomized trial

Intervention

In parallel cohorts, multiple implementations of CBCT-guided online adaptive radiotherapy are studied conform the specific study manual.

Study burden and risks

The extra scans will take more time. Furthermore, the patient is exposed to more radiation caused by the extra scans.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patient with tumor type of one of the cohorts
Age >= 18 years
Scheduled to undergo online adaptive CBCT-guided radiation therapy.
WHO performance score 0*3.
Ability to give oral and written informed consent

Exclusion criteria

Pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-08-2023
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Rotation Simulator
Registration:	No

Ethics review

Approved WMO Date:	07-07-2023
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	NL83893.041.23