Addition of a Focal boost In external beam Radiotherapy for locally advanced prostate cancer by online adaptive MR-guided radiotherapy (AFFIRM trial)

Published: 23-06-2022
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In the present study the clinical feasibility and safety of MR-guided focal boost radiotherapy for patients with locally advanced prostate cancer will be evaluated.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON53565

Source
ToetsingOnline

Brief title
AFFIRM trial

Condition

- Reproductive neoplasms male malignant and unspecified
- Prostatic disorders (excl infections and inflammations)

Synonym
prostate cancer; prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hypofractionation, Isotoxic boost, MR-guided radiotherapy, Prostate cancer

Outcome measures

Primary outcome

The primary endpoint is acute gastrointestinal and genitourinary toxicity,

scored by the Common Terminology Criteria Adverse Events version 5.0.

Secondary outcome

Secondary endpoints are late gastrointestinal and genitourinary toxicity,

quality of life and biochemical disease free survival defined by the Phoenix

consensus definition

Study description

Background summary

External beam radiotherapy combined with androgen deprivation therapy is considered as the treatment of choice for patients with locally advanced non-metastatic prostate cancer with seminal vesicle invasion. In routine practice, patients are treated in conventional fractionation schemes (35-40 fractions) or moderate hypofractionation (20 fractions). The long-term results of the multicentre phase III study (FLAME trial) showed that addition of an isotoxic focal boost to the intraprostatic lesion improves biochemical disease free survival in intermediate to high-risk patients without impacting toxicity and quality of life. This focal boost strategy is now proven for a conventional fractionation scheme (35 fractions). The current trend in radiotherapy for prostate cancer is (extreme) hypofractionation, reducing the number of fractions. For locally advanced prostate cancer, however, the data on extreme hypofractionation are scarce. There are no long term data available on combining a hypofractionated schedule with a focal boost.

Study objective

In the present study the clinical feasibility and safety of MR-guided focal

boost radiotherapy for patients with locally advanced prostate cancer will be evaluated.

Study design

Phase II multicentre intervention study

Intervention

External beam MR-guided (MR-linac) radiotherapy to the prostate and seminal vesicles of 5x7Gy (once weekly) with an isotoxic integrated focal boost up to 50Gy to the intraprostatic tumor as visible on multiparametric MRI.

Study burden and risks

The potential risk of participating in the trial is an increase in toxicity, compared to standard treatment without a focal boost (in 20-40 fractions, 5x/week). The focal boost will be dosed in an isotoxic approach, meaning that the dose constraints to the organs at risk are leading and the boost dose will be up to 50Gy or as high as achievable while respecting the dose to the organs at risk. In the comparable hypoFLAME trial (which excluded patients with -extensive- seminal vesicle invasion) no grade 3 or higher acute toxicity was observed. As the constraints to the organs at risk are identical to the constraints used in the hypoFLAME trial, it is expected that grade 3 of higher acute toxicity will be less than 5%.

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

Men aged 18 years or older with histogically proven prostate carcinoma
Imaging stage T3b (as defined on mpMRI) N0M0
Intraprostatic lesion visible on MRI
Capable of giving informed consent
Participation in the MOMENTUM dataregistry

Exclusion criteria

History of radiotherapy to the pelvis or transurethral resection of the prostate (TURP)
Contraindications for MRI according to the guidelines of the Department of Radiology, inability to lay on a treatment table for 45-60 minutes or severe claustrophobia
Absence of pretreatment PSMA PET CT
WHO performance score > 2
International Prostate Symptom Score >= 15
PSA > 30
Prostate volume >100cc

Study design

Design

Study phase: 2

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-11-2022
Enrollment:	95
Type:	Actual

Ethics review

Approved WMO Date:	23-06-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-11-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-11-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-04-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-03-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	08-01-2025
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL79869.091.22