Towards optimal treatment for high risk prostate cancer; stereotactic pelvic radiotherapy with focal boost to the primary tumor

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Determine the safety (oncological outcome and toxicity) of an comprehensive treatment combining recent advances in the treatment of high risk prostate cancer.

Ethical review	Not approved
Status	Will not start
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON56376

Source
ToetsingOnline

Brief title
HypoPRIME

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: HMC wetenschapsfonds

Intervention

Keyword: boost, optimalization, prostate, stereotactic

Outcome measures

Primary outcome

Biochemical recurrence free survival and late toxicity

Secondary outcome

Overall survival; Metastasis Free survival at 4 years; pattern of failure

(based on PSMA in case of biochemical recurrence)

Study description

Background summary

Recently several randomized trial have shown benefits of changes made to radiotherapy of (high risk) localized prostate cancer patients: A focal boost was shown to improve outcome in men with intermediate/high risk prostate cancer (FLAME trial). Elective lymph node irradiation was shown to improve outcome in high risk prostate cancer patients (POP-RT). (Extreme) hypo fractionation was shown to be safe for low/intermediate risk prostate cancer patients. In addition: the added benefit of ADT (with substantial toxicity) seems reduced with improvements made to treatment and diagnosis in recent years (DART 01/05); own recent work on this topic; to be published)). None off the above were combined into one ideal treatment for high risk prostate cancer.

Study objective

Determine the safety (oncological outcome and toxicity) of an comprehensive treatment combining recent advances in the treatment of high risk prostate cancer.

Study design

Prospective cohort study with matched contemporary controlgroup

Intervention

Hypofractionated pelvic radiotherapy with boost to primary tumor in the prostate

Study burden and risks

The total number of irradiations is reduced from 25 to 5, which reduces the patient's burden compared to standard treatment.

This treatment is expected to have similar outcomes (oncological outcome/ toxicity). This will be evaluated in an interim analysis with clearly defined stopping criteria.

Stopping rule: If short term toxicity >= grade 3 exceeds 8%, no further patients will be included.

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 of age) diagnosed within 6 months before inclusion with high risk prostate cancer:
o T3 based on digital rectal examination AND/OR
o Grade >= 4 AND/OR
o PSA >=20 ug/L
- Indication for elective lymph node irradiation (based on current clinical guidelines) OR N1 on imaging (with a maximum of 4 suspect lymph nodes)

Exclusion criteria

• Prior pelvic radiotherapy
• TransUrethral Resection of the Prostate (TURP) < 3 months ago
• Prostatectomy or other primary treatment for prostate cancer (e.g. HIFU, cryotherapy, etc)
• contraindications to MRI
• no visible lesion on MRI in prostate for boost
• no PSMA-PET scan
• inflammatory bowel disease
• metastatic disease (M1)
• PSA >50
• unsuitable for SBRT or WPRT
• medical history of cancer other than basal cell carcinoma of the skin

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	228
Type:	Anticipated

Ethics review

Not approved

Date:	28-07-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL83398.058.22