Hypofractionated Focal Lesion Ablative Microboost in prostate cancer 2.0

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

Summary

ID

NL-OMON49965

Source
ToetsingOnline

Brief title
Hypo-FLAME 2.0

Condition

- Reproductive neoplasms male malignant and unspecified
- Male genital tract therapeutic procedures

Synonym
prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Ziekenhuis Leuven
Source(s) of monetary or material Support: eigen instelling

Intervention

Keyword: Prostate cancer, prostate carcinoma

Outcome measures

Primary outcome

Acute gastrointestinal and genitourinary toxicity, scored using 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 is one of the standard treatment options for patients with prostate cancer. The overall treatment time of a standard fractionated schedule varies between 7 and 8 weeks (i.e. 35-40 fractions, 5x/week). Recent studies have identified a proportionally longer overall treatment time as a potential adverse factor for treatment outcome in prostate cancer patients who were treated by conventional radiotherapy schedules. Furthermore shortening of the overall treatment time promotes patient convenience. An extreme shortening of the overall treatment time is possible by using hypofractionated treatment schedules with simultaneous integrated intraprostatic tumor boosting to overcome local recurrences*

Study objective

The aim of the present phase II Hypo-FLAME 2.0 study is to investigate whether it is feasible and safe (acceptable acute toxicity) to further reduce the Overall Treatment Time of whole gland SBRT with a simultaneous integrated focal boost for prostate cancer

Study design

Multicenter, single arm phase II study

Intervention

Radiotherapy with simultaneous integrated boost

Study burden and risks

Patients will have to fill in a quality of life questionnaire before and after the radiotherapy treatments. The risk associated with this trial is an increase in toxicity. Since in the current protocol only a small part of the prostate receives an increased dose, unacceptable higher toxicity to the organs at risk is not expected. Furthermore, to achieve equal or less toxicity compared to the current radiotherapy protocols, the dose to the organs at risk will be prioritized. Besides, in the original Hypo-FLAME study no > grade 2 acute toxicity has been observed (unpublished data). Hence, this study is considered as a low-risk trial.

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 >= 18 years with histologically confirmed prostate adenocarcinoma
- Intermediate- or high-risk PCa, defined as at least one of the following risk criteria:
- Clinical stage: T2b, T2c, T3a or T3b with less than 5 mm invasion in the seminal vesicles (defined on MRI) N0 M0
- Gleason sum score >= 7
- PSA >= 10 ng/mL.
- Prostate tumor nodule visible on mpMRI
- Ability to give written informed consent and willingness to return for follow-up

Exclusion criteria

- Prior pelvic radiotherapy or transurethral prostate resection
- Unsafe to have gold fiducial marker implantation, if gold fiducial markers are used for image guidance (non MR-linac)
- Contraindications to MRI according to the Radiology Department guidelines (metal implants, non-compatible cardiac device, allergy to gadolinium, severe renal dysfunction or severe claustrophobia)
- World Health Organization (WHO) performance score > 2
- International prostate symptoms score (IPSS score) >= 15
- PSA > 30 ng/mL

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):	27-11-2020
Enrollment:	83
Type:	Actual

Ethics review

Approved WMO

Date:	25-09-2020
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
ClinicalTrials.gov	NCT04045717
CCMO	NL71504.031.19