EREctile Conservation after prostate radiation Therapy (ERECT); a prospective phase 2 trial

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Investigation of maintenance of erectile function after MR-guided radiotherapy with neurovascular sparing in patients with localized prostate cancer.

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

Summary

ID

NL-OMON50019

Source
ToetsingOnline

Brief title
ERECTtrial

Condition

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

Synonym
Erections, Prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Erectile dysfunction, Localized prostate cancer, MR image guided radiation therapy (MRgRT)

Outcome measures

Primary outcome

Primary endpoint: the incidence of erectile dysfunction (ED) three years after

treatment.

Secondary outcome

Secondary endpoints: erectile dysfunction (at 6, 12 and 24 months),

relapse-free survival, acute and late urogenital and gastrointestinal toxicity,

and patient-reported quality of life.

Study description

Background summary

Erectile dysfunction is a frequent side effect of external radiotherapy (EBRT) for prostate cancer. To date, anatomy-based treatments developed to conserve relevant neurovascular structures, such as the pudenda interna and neurovascular bundles, have not yet been routinely implemented in the clinic. The implementation of magnetic resonance imaging (MRI) in the planning and introduction of *Intensity Modulated Radiotherapy* (IMRT) and *Volumetric Arc Therapy* (VMAT) have improved treatment precision and enabled anatomy-focused external beam radiation and neurovascular sparing treatments made. Spratt et al. Conducted a one-arm phase 2 study to investigate the effect of vascular-sparing IMRT treatments and found significantly improved 2-year erectile function (78%, 95% confidence interval [CI] 71-85%) compared to conventional radiotherapy (42%, 95% CI 38-45%; p <0.001) or nerve-sparing prostatectomy (24%, 95% CI 22-27%; p <0.001). The MRI linear accelerator (MR-Linac) has recently been introduced in the UMCU. This new system enables radiation delivery under highly accurate MRI visualization. The MR-Linac is therefore the most suitable technique for neurovascular-sparing external radiotherapy treatments. Such neurovascular-sparing treatments can significantly improve the degree of erectile function after radiotherapy and thus can improve the quality of life without substantially compromising the

oncological outcome.

Study objective

Investigation of maintenance of erectile function after MR-guided radiotherapy with neurovascular sparing in patients with localized prostate cancer.

Study design

The *EREctile function preservation for prostate Cancer radiation Therapy (ERECT)* single-center phase 2 study. Patients are treated with the MR-Linac up to 5 fractions of 7.25 Gy with neurovascular sparing. All fractions are delivered in the course of two and a half weeks.

Intervention

All patients will receive MR-Linac treatment consisting of 5 fractions of 7.25 Gy with neurovascular sparing (i.e. additional sparing of the neurovascular bundles, internal pudendal arteries, penile bulb and corpora carvernosa). Fractions will be delivered with an overall treatment time of two and a half weeks.

Study burden and risks

Nature and magnitude of the burden and risks associated with participation, benefit and group-relatedness: Participants will receive neurovascular sparing MR-guided radiation therapy (MRgRT) consisting of 5 fractions of 7.25 Gy. The number of fractions and the duration of treatment is comparable to conventional MRgRT, consisting of 5 fractions of 7.25 Gy. No increase in toxicity is expected because the dose limitations for the organs at risk in the neurovascular sparing radiation plan will be identical to a conventional radiation plan (i.e. bladder, rectum, femoral head and anal sphincter). For neurovascular sparing treatment, the protocol is extended to include dose restrictions for newly identified risk organs (ie neurovascular bundles (NVB), arteria pudenda interna (IPA), corpora cavernosa (CC) and bulbus penis (PB)). Sparing these structures can reduce erectile dysfunction after treatment. The dose to the dorsolateral part of the prostate may be lower in the neurovascular radiation plan, since the NVB is close to this part of the prostate. A light dose concession on the dorsolateral part of the prostate is only allowed if the visible tumor on multiparametric MRI is not in the vicinity of the NVB, since underdosing of the dominant index lesion is undesirable for tumor control. A lower dose to the dorsolateral part of the prostate may affect biochemical control in some cases, but we do not expect this to affect overall survival

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

• Age >= 18 years
• Histologically proven adenocarcinoma of the prostate
• Low-risk or intermediate-risk prostate cancer according to NCCN risk categories (low risk: T1c-T2a, Gleason score <=6, and PSA <10 µg/L; intermediate risk: T2b-T2c or Gleason score 7 or PSA 10-20 µg/L)
• Patients with pT1a/b tumor diagnosis after transurethral resection of the prostate (TURP)
• Domain score of 17-25 on the International Index of Erectile Function-5 (IIEF-5) questionnaire
• Karnofsky score of 70-100
• Written informed consent

Exclusion criteria

Use of (neo-)adjuvant androgen deprivation therapy
• High-risk prostate cancer according to NCCN risk categories (T3a or Gleason score 8-10 or PSA >20 µg/L)
• Patients with *bulky* iT3 tumor diagnosis
• Previous pelvic irradiation or radical prostatectomy
• Clinical evidence of metastatic disease
• Patients who meet exclusion criteria for MRI following the protocol of the radiology department of the UMC Utrecht (see appendix I)
• Patients who are incompetent to sign written informed consent

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-07-2021
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	07-10-2020
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
CCMO	NL73192.041.20