DOse volume effects and Fibrosis in the corpora cavernosa After Radiotherapy for prostate cancer
A pilot study

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The first objective of this study is to test the hypothesis that a higher dose to the IPAs and corpora cavernosa is correlated to ED after EBRT. The second objective is to test the hypothesis that RIF in the IPAs and corpora cavernosa is correlated...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON30681

Source
ToetsingOnline

Brief title
DOFAR

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- Sexual function and fertility disorders
- Male genital tract therapeutic procedures

Synonym
carcinoma of the prostate, prostate cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: corpora cavernosa, erectile dysfunction, prostate, radiotherapy

Outcome measures

Primary outcome

The primary endpoint of this study is to analyze the correlation between the

radiation dose in the IPAs and ED after EBRT, based on IIEF scores.

Secondary outcome

The secondary endpoints are to test the hypothesis that RIF in the IPAs and

corpora cavernosa causes ED after EBRT.

Study description

Background summary

Erectile dysfunction (ED) is a side effect after external beam radiotherapy (EBRT) for prostate cancer, affecting 50% to 60% of pre-treatment potent patients. Radiation dose to the corpora cavernosa has the potential to be an important factor in ED after EBRT. Several studies have tried to elucidate the etiology of ED after radiotherapy by using Doppler ultrasound. These studies demonstrated a reduced flow in the cavernosal arteries and venous leakage of the corpora cavernosa in men with ED after EBRT. It is very well possible that the decrease of flow in cavernous arteries is caused by an occlusion higher up, in the IPAs. Untill now, there is no report analyzing dose-volume effects between radiation dose in the IPAs and ED after radiotherapy. Our hypothesis is that the inflow of blood into the corpora cavernosa is reduced by radiation-induced fibrosis (RIF) in the IPAs providing the inflow. By use of MRI it is possible to visualize the IPAs.

Study objective

The first objective of this study is to test the hypothesis that a higher dose

to the IPAs and corpora cavernosa is correlated to ED after EBRT. The second objective is to test the hypothesis that RIF in the IPAs and corpora cavernosa is correlated to ED after EBRT.

Study design

Part A

At first MRI scans will be taken of 5 patients suffering from ED after EBRT. These MRI scans will be performed to see if it is possible to detect RIF in the IPAs and corpora cavernosa.

Part B

Before starting EBRT the International Index of Erectile function (IIEF) 26 questionnaire will be filled out and a MRI scan will be performed. This MRI scan will be matched with the planning CT scan. The IPAs and corpora cavernosa will be contoured on the matched CT-MRI scan.
An IIEF questionnaire will be sent to the patients at 1 and 2 years after EBRT.

If it is possible to detect RIF in Part A of the present study, then the MRI scans will be repeated at 1 and 2 years after EBRT. Two radiologists, blinded for the IIEF scores, will assess whether fibrosis in the IPAs and corpora cavernosa has occured.

Study burden and risks

One or three MRI scans will be made of each patients. This will require I.V. gadolinium chelate contrast. This is a very safe form of contrast, which hardly ever causes side-effects. The benefit for the patient is small, although extra informatin about the tumor could be attained with the MRI scan.
The IIEF has to be filled out one or three times. This takes about 10 minutes.
The patient population of this study is the same patient population that might benefit from this study in the future.

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

Histologically proven prostate cancer
Online setup corrections with gold markers
International Index of Erectile Function erectile function domain score of at least 13

Exclusion criteria

Erectile dysfunction before treatment
Adjuvant hormonal therapy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-12-2007
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	02-05-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL14975.078.07