Contrast Enhanced Ultrasound imaging to support prostate cancer brachytherapy treatment and follow up after treatment

Published: 06-09-2007
Last updated: 08-05-2024

To investigate if contrast enhanced ultrasound can improve prostate brachytherapy outcomes. Besides that we will investigate if contrast enhanced ultrasound can be used as an extra verification of follow up after treatment.

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

Summary

ID

NL-OMON30917

Source
ToetsingOnline

Brief title
contrast enhanced ultrasound of prostate cancer

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC

Synonym
prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Stichting Sonura

Intervention

Keyword: brachytherapy, contrast enhanced ultrasound, prostate, prostate carcinoma

Outcome measures

Primary outcome

Oncological outcomes of adjusted radiation dose with prostate brachytherapy

based on perfusion imaging outcomes.

Secondary outcome

What happens with prostate blood perfusion after treatmetn with prostate

brachytherapy?

Study description

Background summary

Brachytherapy of the prostate is globally used as a treatment for prostate cancer. Because prostate cancer is a multifocal disease, radiation of the entire prostate is necessary. New treatment techniques are being used to increase the radiation dose on those places where cancer existence is proven. Sensitivity and specificity however of the conventional detection and imaging techniques for prostate cancer are low. Contrast enhanced ultrasound can detect abnormal bloodperfusion of the prostate, associated with tumor foci, and thus improve sensitivity and specificity of tumor detection. The information of contrast enhanced ultrasound before treatment can be used to adjust the radiation dose and improve treatment outcomes. The same properties of contrast enhanced ultrasound of the prostate can be used to improve follow up after treatment.

Study objective

To investigate if contrast enhanced ultrasound can improve prostate brachytherapy outcomes. Besides that we will investigate if contrast enhanced ultrasound can be used as an extra verification of follow up after treatment.

Study design

observational investigation

Study burden and risks

Giving the patient an iv-line could be uncomfortable for the patient.

A transrectal ultrasound of the prostate can be experienced as uncomfortable by some patients. However during diagnosing the prostate cancer, the patient already had a transrectal ultrasound of the prostate at least one time. So the patient will know what to expect and would not participate when he experienced the investigation as very unpleasent. The investigation itself will not take longer than 5 minutes.

The risk of contrast agent sonovue is minimal. Literature mentions 1 case of an allergic reaction (0,01%). The most frequently mentioned minor side-effects of microbubble contrast agents are alteration of taste, local pain at the injection site and facial or general flush. These side-effects are transient, mild and rare (1-5%).

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

Biopsy proven prostate cancer, treatment with brachytherapy

Exclusion criteria

severe cardiac problems, severe hypertension

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL17306.018.07