

# Determination of the additional clinical value of contrast enhanced ultrasound imaging for the diagnosis of prostate cancer

Published: 13-10-2006

Last updated: 09-05-2024

see page 5 of the protocol: presentation of the question

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Renal and urinary tract neoplasms malignant and unspecified
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON29721

### Source

ToetsingOnline

### Brief title

Contrast enhanced ultrasound of the prostate

### Condition

- Renal and urinary tract neoplasms malignant and unspecified

### 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:** contrast enhanced ultrasound, prostate, prostate carcinoma

## Outcome measures

### Primary outcome

Parameters of contrast enhanced ultrasound will be correlated and compared to the histology of the resected prostate.

### Secondary outcome

Adverse events of the used contrast agent

## Study description

### Background summary

The sensitivity and specificity of grayscale ultrasound concerning the diagnosis of prostate cancer is low. Based on this it is hard to interpret anomalies seen during the ultrasound. We believe that contrast enhanced ultrasound can improve both sensitivity and specificity. By correlating and comparing the parameters of contrast enhanced ultrasound of the prostate with its carcinoma to the histology of the resected prostate we can determine the additional clinical value of contrast enhanced ultrasound.

### Study objective

see page 5 of the protocol: presentation of the question

### Study design

observational research

### Study burden and risks

Giving the patient an iv-line could be uncomfortable for the patient. However doing the research during the hospitalization before operation means that the patient already has an iv-line and so this will not be an extra burden for the patient.

An ultrasound of the prostate can be experienced as uncomfortable by some patients. However during diagnosing the prostate cancer, the patient already had an ultrasound of the prostate at least once. So the patient will know what to expect and would not participate when he experienced the investigation as very unpleasant. 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

### Public

Academisch Medisch Centrum

meibergdreef 9  
1105 az amsterdam  
NL

### Scientific

Academisch Medisch Centrum

meibergdreef 9  
1105 az amsterdam  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Biopsy proven prostate carcinoma, treatment by (laparoscopic) radical prostatectomy

## 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: Recruitment stopped

Start date (anticipated): 26-09-2006

Enrollment: 200

Type: Actual

## 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	NL13542.018.06

## Study results

Date completed:	01-12-2016
Actual enrolment:	250