# Evaluation of the clinical value of contrast enhanced ultrasound in the diagnostic and follow-up of renal cell cancer

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We would like to investigate the role of CE-US with Sonovue (Bracco) in patients with RCC. Our primary objective is to establish the diagnostic accuracy of CE-US in renal masses suspicious for RCC.Our secondary objective is to establish the pattern…

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Renal and urinary tract neoplasms malignant and unspecified |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON31004

**Source**
ToetsingOnline

**Brief title**
Contrast enhanced ultrasound in renal cell carcinoma

### Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Renal disorders (excl nephropathies)

**Synonym**
renal cancer, renal cell carinoma

**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, renal cell carcinoma

## Outcome measures

### Primary outcome

Our primary objective is to establish the diagnostic accuracy of CE-US in renal

masses suspicious for RCC.

### Secondary outcome

Our secondary objective is to establish the pattern of vascularisation in the

different sub-types of RCC.

# Study description

### Background summary

Kindney cancer accounts for 3% of all new cancers in the world. Of these kidney cancers 85% are carcinomas derived from the epithelium (renal cell carcinomas). The incidence of renal cell carcinoma (RCC) is steadily rising. In the United States 51190 new cases and 12,890 deaths are expected in 2007.
Diagnostic of RCC is based on radiological features and once the suspicion is arised, surgery (radical or nefron sparing) remains the strategy of choice. Although most of these tumors are initially found by ultrasound (US), the gold-standard for imaging kidney tumors is a four-fase contrast enhanced abdominal CT-scan (CE-CT). Main disadvantage of this exploration is the radiation exposure and the possible adverse effects of the contrast, mainly allergy and nefrotoxity. For patients in whom formal contraindication exists for CE-CT, contrast enhanced magnetic resonance imaging (CE-MRI) is the modality of choice. However CE-MRI is expensive and time consuming and limited by physical patient conditions. CE-CT is also regularly performed in the follow-up of patients having received a nefron sparing surgery .
Since 1968 contrast agents are being developed to be used with ultrasound10. These contrast agents are intravenously administered, well tolerated and

non-nephrotoxic. These contrasts are vascular selective and consists of microbubbles of inert gases encased in a biodegradable phospholipids shell. They are smaller than the erythrocytes and able to circulate in vessels of 2 *m. The newest CE-US methods are based on the characteristics of the nonlinear bubble behavior offering a high sensitive en selective imaging of the contrast agent. Some techniques enable distinction between the non-linear signals reflected by the contrast agent and the linear responses of the normal tissue. This makes simultaneous viewing of tissue-only and contrast-only images possible. One of these methods is described in detail in a publication by Phillips. Various microbubble contrast agents have been registered for use in Europe; in the Netherlands, Sonovue® (Bracco) is approved for general use.

Contrast enhanced ultrasound (CE-US) is performed in diagnostic and experimental settings in various institutions throughout the world. In oncology CE-US is mainly used for the characterization and detection of hepatic masses. Its use in kidney, spleen and pancreas are currently under investigation. In our institute we are investigating the use of CE-US in the diagnostic of prostate cancer. The preliminary results are promising.

Experience with CE-US in Renal Masses
The use of CE-US for imaging of renal masses was first described in 199420 in patients with renal cell carcinoma (RCC) and renal insufficiency. However for detection and characterization of renal cell cancer, only small studies are available. All authors conclude that differentiation between benign and malignant renal masses could be possible using ultrasound after the injection of microbubbles.

**Study objective**

We would like to investigate the role of CE-US with Sonovue (Bracco) in patients with RCC.
Our primary objective is to establish the diagnostic accuracy of CE-US in renal masses suspicious for RCC.
Our secondary objective is to establish the pattern of vascularisation in the different sub-types of RCC.

**Study design**

We will preform CEUS at 100 patients with renal cell carcinoma who will be treated by either (partial) nefrectomy or cryosurgery. Patients treated with nefronsparing therapie will also be followed-up with CEUS.
Patients with complicated cysts who will be followed-up by CT or MRI a CEUS will be performed on their next visit to the out-patient clinic. The images gained with the CEUS will be stored and descriped. These images will be compered with the CT and the histology. On basis of this we will make a classification.

**Study burden and risks**

Patients will be asked to undergo 1 or more CE-US investigations before and after treatment for renal cell cancer. Investigations will be planned together with hospital visits or carried out during hospital admission as much as possible. This imaging tool is part of standard patient care in various institutions and the microbubble agent is marketed for general use in the Netherlands. Furthermore, ultrasound is considered a safe investigation because of the use of non-ionizing radiation. The side effects of the microbubble contrast agent are minimal, as described above. All investigations will be carried out according to the recommendations in the published

# 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

Patients with renal cell carcinoma who wil be operated or patients with complicated cysts who will be followed-up

### Exclusion criteria

severe cardial co-morbidity, New York Heart Association class IV cardiac failure.

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-03-2006 |
| Enrollment: | 100 |
| Type: | Anticipated |

## Ethics review

Approved WMO

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|---|---|
| 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 | NL16473.018.07 |