

# Validation of a strategy to identify benign pathology in patients operated for a complex renal cyst. (RECIST: REnal Cysts: Indications for Surgery Trial)

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To validate a diagnostic panel existing of MRI, CEUS, and FNA, which can differentiate benign pathology from malignant pathology of complex renal cysts.

<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-OMON37800

### Source

ToetsingOnline

### Brief title

RECIST

### Condition

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

### Synonym

kidney cysts, Renal cysts

### 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:** (Partial) nephrectomy, Carbonic anhydrase IX (CAIX), Diagnostic path, Renal cysts

## **Outcome measures**

### **Primary outcome**

Sensitivity of the diagnostic panel.

### **Secondary outcome**

- o Specificity of the diagnostic panel.
- o Sensitivity and specificity of the MRI-test.
- o Sensitivity and specificity of the CEUS-test.
- o Sensitivity and specificity of the FNA-test.
- o Sensitivity and specificity of the combination of the MRI-test and the CEUS-test.
- o Sensitivity and specificity of the combination of the MRI-test and the FNA-test.
- o Sensitivity and specificity of the combination of the CEUS-test and the FNA-test.
- o Positive predictive value of the MRI-test.
- o Positive predictive value of the CEUS-test.
- o Positive predictive value of the FNA-test.
- o Positive predictive value of the combination of the MRI-test and the CEUS-test.
- o Positive predictive value of the combination of the MRI-test and the FNA-test.
- o Positive predictive value of the combination of the CEUS-test and the

FNA-test.

- o Proportion of patients with a complication of the diagnostic panel
- o Number of upgraded lesions that are Bosniak IIF on CT.

## Study description

### Background summary

As a result of the widespread and increasing use of abdominal imaging, the incidence of small renal masses, including renal cysts is increasing. Based on contrast enhanced CT scan, lesions can be classified as simple or complex. Approximately 50% of these complex cysts prove to be benign on resection. It is currently not possible to differentiate benign from malignant disease before surgery. Therefore, the standard of care is to advise patients to undergo a partial nephrectomy. Cohort studies show that 5-10% of patients experience major urological complications.

### Study objective

To validate a diagnostic panel existing of MRI, CEUS, and FNA, which can differentiate benign pathology from malignant pathology of complex renal cysts.

### Study design

Prospective, observational, cohort study.

### Study burden and risks

There are a couple of risks associated with the use of contrast agent for ultrasonography and MRI. Patients with a known allergy to contrast agents are therefore excluded from participation in the trial (see also the exclusion criteria). Known side effects of the use of contrast agents are: serious allergic reactions, headache, reaction on the site of injection (bruise, redness, numb feeling), pain at the injection site, hypersensitive reaction (e.g. abnormal redness of the skin, slow heart beat, low blood pressure, or, rarely, anaphylactic shock).

## 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

- Bosniak IIF, III, or IV renal cyst on contrast enhanced CT scan.
- Fit for surgery.
- Signed informed consent.
- Age  $\geq$  18 years.

### Exclusion criteria

- Pregnancy or breastfeeding.
- Women unwilling to use an effective birth control method during study participation.
- Known allergy to contrast agents or sulphur hexafluoride micro bubbles.
- Any clinically unstable cardiac condition within 7 days prior to contrast agent administration such as:
  - o evolving or ongoing myocardial infarction.
  - o typical angina at rest.

- o significant worsening of cardiac symptoms.
- o recent coronary artery intervention or other factors suggesting clinical.
- o instability (e.g., recent deterioration of Electrocardiogram (ECG), laboratory or clinical findings).
- o acute cardiac failure, class III/IV cardiac failure.
- o severe cardiac rhythm disorders.
- o right-to-left shunts.
- Severe pulmonary hypertension (pulmonary artery pressure >90 mmHg) or uncontrolled systemic hypertension or respiratory distress syndrome.
- Severe cardiac condition.
- Vulnerable for convulsions.
- Presence of a pacemaker or other implants or clamps or other contra-indication for MRI.
- Claustrophobia
- Renal insufficiency (Glomerular Filtration Rate (GFR) < 30 ml/min).

## 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): 14-08-2012

Enrollment: 80

Type: Actual

## Ethics review

Approved WMO

Date: 08-05-2012

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

ID: 28890

Source: NTR

Title:

### In other registers

Register	ID
CCMO	NL39734.078.12
OMON	NL-OMON28890