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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	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 >= 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: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL39734.078.12
OMON	NL-OMON28890