Studie naar een nieuwe methode om vast te kunnen stellen of een niercyste goed- of kwaadaardig is.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28890

Source
NTR

Brief title
RECIST

Health condition

Niercysten, renale cysten (kidney cysts, renal cysts)

Sponsors and support

Primary sponsor: Erasmus MC (Dept. Urology)
Source(s) of monetary or material Support: Erasmus MC (Dept. Urology)

Intervention

Outcome measures

Primary outcome

Sensitivity of the diagnostic panel.

Secondary outcome

1. Specificity of the diagnostic panel;

2. Sensitivity and specificity of the MRI-test;

3. Sensitivity and specificity of the CEUS-test;

4. Sensitivity and specificity of the FNA-test;

5. Sensitivity and specificity of the combination of the MRI-test and the CEUS-test;

6. Sensitivity and specificity of the combination of the MRI-test and the FNA-test;

7. Sensitivity and specificity of the combination of the CEUS-test and the FNA-test;

8. Positive predictive value of the MRI-test;

9. Positive predictive value of the CEUS-test;

10. Positive predictive value of the FNA-test;

11. Positive predictive value of the combination of the MRI-test and the CEUS-test;

12. Positive predictive value of the combination of the MRI-test and the FNA-test;

13. Positive predictive value of the combination of the CEUS-test and the FNA-test;

14. Proportion of patients with a complication of the diagnostic panel;

15. Number of upgraded lesions that are Bosniak IIF on CT.

Study description

Background summary

Background of the study:

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.

Objective of the study:

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 population:

Patients with a complex renal cyst on a contrast enhanced CT scan are included in this trial.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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).

Countries of recruitment:

The Netherlands.

Study objective

N/A

Study design

Maximal 4 visits in 15 weeks.

Intervention

Diagnostic panel:

1. Contrast Enhanced UltraSound (CEUS);

2. Magnetic Resonance Imaging (MRI) with contrast;

3. Fine Needle Aspiration (FNA).

Contacts

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Eligibility criteria

Inclusion criteria

1. Bosniak IIF, III, or IV renal cyst on contrast enhanced CT scan;

2. Fit for surgery;

3. Signed informed consent;

4. Age ≥ 18 years.

Exclusion criteria

1. Pregnancy or breastfeeding;

2. Women unwilling to use an effective birth control method during study participation;

3. Known allergy to contrast agents or sulphur hexafluoride micro bubbles;

4. Any clinically unstable cardiac condition within 7 days prior to contrast agent administration such as:

A. Evolving or ongoing myocardial infarction;

B. Typical angina at rest;

C. Significant worsening of cardiac symptoms;

D. Recent coronary artery intervention or other factors suggesting clinical;

E. Instability (e.g., recent deterioration of Electrocardiogram (ECG), laboratory or clinical findings);

F. Acute cardiac failure, class III/IV cardiac failure;

G. Severe cardiac rhythm disorders;

H. Right-to-left shunts.

5. Severe pulmonary hypertension (pulmonary artery pressure >90 mmHg) or uncontrolled systemic hypertension or respiratory distress syndrome;

6. Severe cardiac condition;

7. Vulnerable for convulsions;

8. Presence of a pacemaker or other implants or clamps or other contra-indication for MRI;

9. Claustrophobia;

10. Renal insufficiency (Glomerular Filtration Rate (GFR) < 30 ml/min).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-06-2012
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-05-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37800
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3269

Register	ID
NTR-old	NTR3422
CCMO	NL39734.078.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37800

Study results

Summary results
N/A