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

Gepubliceerd: 04-05-2012 Laatst bijgewerkt: 15-05-2024

N/A

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28890

Bron
NTR

Verkorte titel
RECIST

Aandoening

Niercysten, renale cysten (kidney cysts, renal cysts)

Ondersteuning

Primaire sponsor: Erasmus MC (Dept. Urology)
Overige ondersteuning: Erasmus MC (Dept. Urology)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Sensitivity of the diagnostic panel.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

N/A

Onderzoeksopzet

Maximal 4 visits in 15 weeks.

Onderzoeksproduct en/of interventie

Diagnostic panel:

1. Contrast Enhanced UltraSound (CEUS);

2. Magnetic Resonance Imaging (MRI) with contrast;

3. Fine Needle Aspiration (FNA).

Contactpersonen

Publiek

Dept. Urology
Erasmus MC
's-Gravendijkwal 230
P.C.M.S. Verhagen
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7040704

Wetenschappelijk

Dept. Urology
Erasmus MC
's-Gravendijkwal 230
P.C.M.S. Verhagen
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7040704

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-06-2012
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-05-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37800
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3269
NTR-old	NTR3422
CCMO	NL39734.078.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37800

Resultaten

Samenvatting resultaten
N/A