Contrast ultrasound dispersion imaging (CUDI) as a diagnostic modality in the diagnosis of renal cell carcinoma.

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The main goal of this study is to assess whether CUDI-quantification of CEUS can successfully be correlated to malignant pathology results of kidney tissue.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON49171

Source
ToetsingOnline

Brief title
CUDI-RCC

Condition

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

Synonym
kidney cancer, renal cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CUDI, kidney, renal cancer, ultrasound

Outcome measures

Primary outcome

Parameters defined by CUDI-quantification that correlate with the pathology

results.

Secondary outcome

Nvt

Study description

Background summary

Renal cell carcinoma (RCC) is a neoplasm that represents 2-3% of all cancers. Nowadays, clinical diagnosis is based on a combination of physical examination, laboratory findings, and imaging. Most kidney tumors are diagnosed by an abdominal ultrasound, CT scan or MRI that is performed for other medical reasons. On imaging, a highly suspicious renal mass can be diagnosed, however, differentiating between benign or malignant is not yet possible. To reveal the histology of a suspicious tumor, a renal tumor biopsy (RTB) can be performed. RTB*s are performed under local anesthesia and can be performed by either core needle or fine needle aspiration. The morbidity of RTB*s is low, but not non-existent. Risks of the biopsy procedure include haematomas, infection and recently there has been some discussion about possible tumor seeding in the needle tract. Another diagnostic modality with less risks is therefore needed.

Contrast enhanced ultrasound (CEUS) is an already prior researched technique that could fill this gap. With this technique, an ultrasound scan is made with the support of ultrasound contrast agents, so called microbubbles. By using those bubbles, micro vasculature can be visualised. Prior research has shown that CEUS has a sensitivity of 93% for characterising kidney laesions. De specificity however was mediocre, around 72.5%. Possible problems with CEUS leading to this low specificity are the subjective and difficult interpretation, which makes the interpretation of CEUS images difficult outside of centres of excellence. For this reason, a more objective and reliable interpretation by quantification of CEUS is needed.

Together with the Technische Universiteit Eindhoven, previous researchers in Amsterdam UMC have developed a quantification method based on the diffusion or dispersion of contrast agent in the tissue: Contrast Ultrasound Dispersion Imaging (CUDI). The method builds on the interpretation of the contrast agent kinetics as a convective dispersion process. By using CUDI, local parameters kan by extracted in order to build a parametric map of dispersion that can visualise underlying microcirculation.

Study objective

The main goal of this study is to assess whether CUDI-quantification of CEUS can successfully be correlated to malignant pathology results of kidney tissue.

Study design

This study will be set up as a prospective, mono center, pilot study. This is a study in which patients that have already been planned for a partial or radical nephrectomy will receive a bolus of contrast fluid, prior to the nephrectomy and after start of anesthesia. After this bolus, CEUS-images of the kidney will be made. Those images will be saved and, at a later moment, be quantified by means of CUDI. Also, we will investigate whether this quantification can be correlated to a pathology result.

Study burden and risks

There is a small anticipated risk for participants. After use in millions of patients, adverse events to the both contrast agents appear to be transient, mild and rare. The side effects of the ultrasound contrast agent mostly consist of transient alteration of taste, local pain at the injection site and facial or general flush. In rare cases allergic reaction is described. For more information see section 6 (Ultrasound and SonoVue® contrast agent). The additional targeted biopsies pose a minor increase in the risk of infection. The risk of infection will be minimized by providing an antibiotic prophylaxis, as part of the standard care, and pausing of anticoagulant medication when it is necessary and safe (depending on the indication for anticoagulant therapy and type of anticoagulants used).

Patients will be informed of the risk during intake, and it will be described in the study information.
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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

· age * 18 years
· signed informed consent
· scheduled for a radical- or partial nephrectomy for the suspicious of a renal tumor.

Exclusion criteria

· Earlier treatment of renal masses
· History of any clinically evidence of cardiac right-to-left shunts
· Severe pulmonary hypertension (pulmonary artery pressure >90 mmHg) or uncontrolled systemic hypertension or respiratory distress syndrome
· Has any medical condition or other circumstances which would significantly decrease the chances of obtaining reliable data, achieving study objectives, or completing the study
· Is incapable of understanding the language in which the information for the

patient is given
· Tumor cannot be visualized/localized on ultrasound imaging

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2020
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	12-07-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	21-05-2021
Application type:	Amendment
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	NL73872.018.20