Feasibility of CT-guided percutaneous needle puncture for kidneys with CASone system

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The aim of this study is to demonstrate the feasibility of CBCT-based stereotactic navigation to perform a better and optimal renal access puncture, which may enable higher stone free rates. This may lower intraoperative ERD during PCNL with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urolithiases
Study type	Observational invasive

Summary

ID

NL-OMON51258

Source
ToetsingOnline

Brief title
Capture

Condition

- Urolithiases

Synonym
kidney stones, nephrolithiasis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CASOne, CT-guided, PCNL, Percutaneous puncture

Outcome measures

Primary outcome

Primary Endpoint:

The primary endpoint of precise kidney access with CT-based stereotactic navigation CASone system is the technical success rate. This is defined as the successful puncture of the intended calix without needle repositioning.

Secondary outcome

Secondary Endpoints:

We will evaluate the following parameters:

- Accuracy:

o Distance between planned target and actual needle tip

o Angle between planned needle trajectory and actual needle

- Radiation dose in mSv

- Procedure time

- Number of postoperative imaging investigations during the follow-up period of six weeks

- Achievement of stone-free rate

- Complications

Study description

Background summary

Nephrolithiasis has a prevalence of 5.5% in the general population and a peak incidence between the age of 30-50 years. The life time risk of a renal stone in the Western world is 10-15%.
According to EAU guidelines large renal calculi should be considered for primary PCNL treatment. PCNL is more invasive than ureteroscopy with subsequently higher complication rates including bleeding and sometimes blood transfusions. Therefore, in PCNL the most important step to minimize complications and achieve the highest success rate, is puncture of the calyx of choice for optimal access to the kidney. Especially with multiple kidney stones in different poles, entering of the kidney via the appropriate access may enable the urologist to reach every angle of the kidney and achieve a high stone-free rate. Despite this ideal scenario, multiple tracts may be needed for complete stone removal. Obviously, this is not favorable to the patient and may increase the risk for complications like bleeding and lead to a longer convalescence time. The greatest challenge during surgery is to translate preoperative 2D CT scan images to a real-life 3D approach of the kidney. It frequently occurs that a different calyx is punctured from the initially planned one, for instance a dorsally located instead of a ventrally located calyx. This problem may be solved with 3D augmented reality or image-guided navigation surgery. General shortcomings in image-guided surgery are the anatomical changes of kidney position between preoperative imaging in supine position and intraoperative lateral decubitus or prone position. Furthermore, intraoperative kidney location may change by respiration movements. With intraoperative CBCT scan imaging and image-guided navigation for kidney puncture these shortcomings may be overcome.
The potential features of the CASone system have previously been shown in reports for hepatocellular carcinoma. Stereotactic image-guided microwave ablation (SMWA) is performed with CT-guidance with needle trajectory, ablation planning and automatic single-marker patient registration. Needle placement and ablation coverage was controlled by image fusion. SMWA is a safe and efficient treatment for HCC offering a curative treatment approach in general and in particular for lesions not detectable on conventional imaging or untreatable due to difficult anatomic locations. The first reports about the CASone system for kidney tumors have appeared (www.cascination.com), but no publications in the field of kidney stone approach and treatment exist. As the CASone system is a CT-based stereotactic navigation system we have to carefully evaluate its merits but also the downsides like radiation exposure.

Study objective

The aim of this study is to demonstrate the feasibility of CBCT-based stereotactic navigation to perform a better and optimal renal access puncture, which may enable higher stone free rates. This may lower intraoperative ERD during PCNL with fluoroscopy and eventually will lead to less CT scans being performed during follow-up. We expect the radiation doses of CBCT-based navigation to be within the acceptable range for intraoperative imaging

procedures.

Study design

Prospective explorative study

Study burden and risks

Anticipated clinical benefits:
The CT-based stereotactic navigation system for precise positioning of the needle during PCNL potentially improves the access to the kidney. Instead of a 2D ultrasound-guided or fluoroscopy based access to the kidney, this approach enables us to perform an intraoperative 3D reconstruction of the kidney position and image-guided navigation access of the needle into the kidney. Ideally, this will lead to optimal kidney entrance without necessity for extra needle punctures and subsequently to higher accuracy of stone removal and stone-free rate. For this feasibility study the first step is to evaluate whether access to the kidney with this navigation technique is possible and safe. The CASone system measures the accuracy of needle position after puncture with an intraoperative placement planning. Therefore, direct feedback on exact needle tip position is provided.

Anticipated adverse events:
Potentially extra radiation dose is given to these patients with the intraoperative CBCT round. Therefore, we evaluated the effective radiation dosis (ERD) of the previous 20 patients who underwent an PCNL in our hospital. The access to the renal collecting system has been performed with a combination of ultrasound and fluoroscopy guidance. The mean ERD during the whole procedure was 1.4 mSv, which is comparable to the literature (1-9mSv). For CBCT stereotactic navigation an ERD of maximally 3.2 mSv per rotation is anticipated, which is acceptable, please see enclosed Radiation Ethics Form for further clarification.
Hypothetically, higher stone-free rate reduces the number of routine plain radiography of the kidney (0.1-0.3 mSv) or a non-enhanced CT-scan (4.5 mSv) during follow-up on the outpatient clinic. In the historical cohort, we performed non contrast CT-scan in 11/20 patients, of which 6 had re-interventions (including additional intraoperative radiation exposure) and 5 went into intensive follow-up with imaging because of residual stones. Routine plain radiography of the kidney was performed in 17/20 patients. As more accurate kidney access and therefore possibly improved stone removal might be expected from CASone, our study patients may eventually receive lower ERDs than patients who undergo routinely performed PCNL. Of course this will be measured and is part of the follow-up and evaluation in this group.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Men / Woman > 18 year
Indication for PCNL (EAU guidelines 2020)

Exclusion criteria

Untreated urinary tract infection
Anatomical abnormalities preventing safe PCNL access or surgical prone positioning
Absolute indication for the continuation of anticoagulant medication
Potentially malignant kidney tumor

Pregnancy

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):	09-03-2022
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	26-07-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL77003.091.21