Intra-operative cone-beam computed tomography for detecting residual stones in percutaneous nephrolithotomy, a randomized controlled trial

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Determining the added value of cone-beam computed tomography in percutaneous nephrolithotomy, by measuring differences in the stone-free rates for patients with cases in which a cone-beam CT-scanner is used versus patients with cases in which no...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Urolithiases
Study type	Interventional

Summary

ID

NL-OMON54945

Source
ToetsingOnline

Brief title
Intra-operative cone-beam CT for detecting residual stones in PCNL

Condition

- Urolithiases

Synonym
Kidney stones, nephrolithiasis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cone-Beam Computed Tomography, Kidney calculi, Nephrolithotomy, percutaneous, Residual fragments

Outcome measures

Primary outcome

The main endpoint in this study is the stone-free status as assessed four weeks post-operatively by low-dose non-contrast abdominal CT.

Secondary outcome

Secondary endpoints are the amount of PCNL procedures required per episode of 3 months starting from the first PCNL procedure and the amount of stone-related events registered within a period of 12 months.

Study description

Background summary

Percutaneous nephrolithotomy is the standard surgical treatment method for large kidney stones. Obtaining a stone-free status is the main goal of this surgical procedure. However, residual stones remain in many cases where the urologist expected to have reached a stone-free status. Partly because of this, re-intervention rates are high and stone-free rates show room for improvement. Cone-beam computed tomography (CBCT) allows for intra-operative cross-sectional and threedimensional imaging of the urinary tract. In this way, any imaged residual fragments can be extracted in the same procedure, expectedly leading to increased single step stone free rates.

Study objective

Determining the added value of cone-beam computed tomography in percutaneous nephrolithotomy, by measuring differences in the stone-free rates for patients with cases in which a cone-beam CT-scanner is used versus patients with cases in which no cone-beam CT-scanner is used.

Study design

This study is a randomized-controlled trial. Patients will be randomized into two even groups during their percutaneous nephrolithotomy. One group will receive an intra-operative cone-beam CT-scan, whilst the other group will undergo the standard procedure without an intra-operative CT-scan. The randomization occurs at the end of the procedure, at the point where the urologist would have otherwise terminated the procedure.

Intervention

The intervention is an intra-operative cone-beam CT-scan. After performing the intra-operative CT-scan, there is a possibility of either continuing the procedure and possibly extracting extra residual fragments, or terminating the procedure if no (retrievable) residual fragments are imaged.

Study burden and risks

The main risks for participating patients consist of an added radiation exposure and added surgery time if allocated to the interventional group. The added radiation exposure is calculated to be 1,5-2 mSv. Surgery time needed for preparation, performing and interpreting an intra-operative cone-beam CT-scan is around 8 minutes, according to our recently conducted pilot-study. If imaged residual fragments are extracted, the median total extra surgery time needed in that pilot-study was 20 minutes.
Patients will not know to which group they are allocated to until after the surgery procedure, since they are under anesthesia during the randomization process.

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

- Scheduled for percutaneous nephrolithotomy in the UMCG
- Intention to obtain a stone-free status in the upcoming procedure
- Obtained written informed consent
- Above 18 years of age

Exclusion criteria

Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-01-2020
Enrollment:	320
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-05-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL70728.042.19