Percutaneous Nefrolithotomy (PCNL) with MITeC: intraoperative CT-guided evaluation of stone free rate.

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The aim of this study is to demonstrate an advantage of intraoperative CT-guided evaluation to ensure that the patient is stone free. If there a still fragments visible they are removed to prevent re-interventions in the future.

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

Summary

ID

NL-OMON43076

Source
ToetsingOnline

Brief title
PCNL with intraoperative CT-guided evaluation of stone free rate

Condition

- Urolithiases

Synonym
kidney stones

Research involving
Human

Sponsors and support

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

Intervention

Keyword: PCNL with MITeC

Outcome measures

Primary outcome

Difference in stone free rate after one procedure between PCNL with and without

MITeC: intraoperative evaluation of stone free rate with CT scan.

Secondary outcome

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Study description

Background summary

Nephrolithiasis is a common disease with a prevalence of 5.5% in the general population.The life time risk of a renal stone in the Western world is 10-15%.

Over the past decade, computed tomography (CT) has become the most common imaging modality for renal colic, due to its diagnostic accuracy for kidney stones with a sensitivity of 99% and specificity of 100%. Stone site and size can be easily measured. In the latest Dutch guidelines the CT is therefore stated as gold standard.

Large symptomatic renal calculi often need active treatment and percutaneous nephrolithotomy (PCNL) has been accepted as highly effective treatment of these renal calculi. Although a minimally invasive endourological technique, PCNL is an operation with reasonable amount of complications and does not always render the patient stone free. During the stone treatment only fluoroscopic guidance is used. This will identify large radiopaque stones such as calcium oxalate, and cysteine stones, but will miss radiolucent stones i.e. uric acid stones an may miss small stones or stones overlying bony structures and the access sheet. So, pre-operative optimal imaging is performed with a low-dose CT scan and during PCNL surgery only suboptimal imaging is performed with ultrasonic and fluoroscopic imaging. The stone free rate after PCNL is thereby overestimated.

Residual fragments post-PCNL give a risk of a symptomatic stone episodes and/or the need for auxiliary treatments. Furthermore, the retreatment rates for residual fragments <=2 mm did not significantly differ from residual fragments

larger than 2 mm, suggesting that any residual fragment may be associated with high risk of retreatment. So, it is important to get the patient completely stone free.

Study objective

The aim of this study is to demonstrate an advantage of intraoperative CT-guided evaluation to ensure that the patient is stone free. If there a still fragments visible they are removed to prevent re-interventions in the future.

Study design

Explorative study of 20 patients with unilateral symptomatic nephrolithiasis and the indication of PCNL according to the EAU/Dutch guidelines with whom PCNL with MITeC shall be performed and will be compared to the last (consecutive) 20 patients of the historical database and literature

In the future a randomized controled trail could be performed.

Study burden and risks

By using the 5s DCT Body CARE protocol this will lead to a ERD of 5 mSv.

But when the patient is stone free routine plain radiography of the kidney (0.1-0.3 mSv) or a non-enhanced CT-scan (4.5 mSv) on the outpatient clinic will not be necessary. If the patient turns out to be not completely stone free on the intraoperative CT-scan, the residual fragments can be removes in the same session. This means that additional radiation exposure during an auxilliary procedure will be spared.

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

Men/Woman >18 year with indication for PCNL according tot EAU/NVU (2015) guidelines

Exclusion criteria

Pre-excisting access tract (nephrostomy catheter)
Active urinary tract infection
Anatomical abnormality as barrier for PCNL access or prone positioning of the patient
Absolute indication for the continuation of anticoagulant medication
Anaeshesiological objections against prone positioning during the operation
Pregnancy

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):	25-06-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	01-12-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-10-2017
Application type:	Amendment
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	NL59090.091.16