Intra-operative cone-beam CT for detecting residual stones

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Using Cone-Beam CT in percutaneous nephrolithotomy for detecting residual stones increases one-step stone-free rates and lowers the occurrence of stone-related events.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29622

Bron
NTR

Verkorte titel
CAPTURE

Aandoening

Urolithiasis

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: UMCG, self-funded

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main endpoint in this study is the stone-free status as assessed four weeks postoperatively

by low-dose non-contrast abdominal CT (NCCT).

Toelichting onderzoek

Achtergrond van het onderzoek

Percutaneous nephrolithotomy (PCNL) 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 stonefree
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.

The objective of this study is to determine 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.

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 conebeam
CT-scan, whilst the other group will undergo the standard procedure without an intraoperative
CT-scan. The randomization occurs at the end of the procedure, at the point where the urologist would have otherwise terminated the procedure.

The study population consists of all patients above 18 years of age in the UMCG that undergo percutaneous nephrolithotomy with the intention to become stone-free. Some patients will drop-out if during the surgery it becomes clear that making a cone-beam CT would have no consequences.

The main endpoint in this study is the stone-free status as assessed four weeks postoperatively
by low-dose non-contrast abdominal CT, as is standard follow-up procedure.
Secondary endpoints are the amount of PCNL procedures required per episode of 3 months starting from the first PCNL procedure, the stone-free rates at the end of an episode of 3 months as assessed by low-dose abdominal CT and the amount of stone-related events registered within a period of 12 months.

Doel van het onderzoek

Using Cone-Beam CT in percutaneous nephrolithotomy for detecting residual stones increases one-step stone-free rates and lowers the occurrence of stone-related events.

Onderzoeksopzet

October 2019 - December 2019: Preparation period (MEC application, protocol and database creation)
January 2020: Start of study
Approx. 2024: Interim analysis (half of study population has completed 1-year follow-up)
Approx. 2026: End of inclusion period
Approx. 2027: Study completion
2027 onwards: Publication

Onderzoeksproduct en/of interventie

The intervention is the use of an intra-operative cone-beam CT-scanner.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Scheduled for percutaneous nephrolithotomy
- Obtained written informed consent

- 18 years or older
- Fluent in Dutch or English language

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Pregnancy during planned surgery

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2020
Aantal proefpersonen:	320
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8168
Ander register	METC UMCG : ABR NL70728.042.19

Resultaten