Stent or Nephrostomy

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Hypothesis: Percutaneous nephrostomy is non inferior to retrograde double J catheter regarding time to clinical recovery. Secondly, patient reported outcome measures (PROMS) comparing treatment room and OR settings of drainage procedures will most...

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

Summary

ID

NL-OMON22950

Source
Nationaal Trial Register

Brief title
STONE study

Condition

- Urolithiases

Health condition

urolithiasis

Research involving
Human

Sponsors and support

Primary sponsor: Leading the Change
Source(s) of monetary or material Support: ZonMw

Intervention

- Surigical procedure

Explanation

Outcome measures

Primary outcome

The primary outcome parameter is time to clinical recovery. Clinical recovery is defined as reaching one or more of the following criteria. The mandatory amount of criteria to achieve clinical recovery is dependent on the indication for placement of a PCN or a JJ. - If indication for drainage is infection: improvement of infection, indicated by a decrease of WBC in two executive laboratory results and below 15.000 mm3 and a body temperature of 36-38.5 C. and/or - If indication for drainage is untreatable pain: Numeric rating score (NRS) considering pain resulting from a renal colic is improved and < 3 points and/or - If indication for drainage is deterioration of kidney function: improvement of creatinine/ Glomerular Filtration Rate (GFR) in two executive laboratory results It may occur that the indication for drainage is a combination of the above named indications. Clinical recovery will then be reached in case all parameters related to the different indications are within the set range.

Secondary outcome

Secondary outcomes are further clinical data, PROMS (measured by the EQ-5D-5L, NRS, a satisfaction scale and a catheter questionnaire) and societal costs (measured by a disease-specified iMCQ questionnaire).

Study description

Background summary

Rationale If a stone obstructs the ureter and impairs urine-efflux from the kidney this may cause infection, pain resulting from a renal colic and/or renal impairment. Drainage of the kidney may be necessary and can be established by placement of either a percutaneous nephrostomy (PCN) or a retrograde double J catheter (JJ). Considering method of drainage, setting, room in which drainage procedures takes place and anesthesia method, there are in fact 16 different approaches for drainage available, each with its own consequences for the patient and on expenses. Although evidence is poor, both methods of drainage are to be considered as equal.[1] This is reflected by the differences in preference between different countries.[2] In 2016 the Dutch association for urology (Nederlandse Vereniging voor Urologie (NVU)) marked this subject as one of the primary knowledge gaps in urology in The Netherlands and gave it priority on the national knowledge agenda for urology.[3] From patients' as well as from societal perspective it is of importance that the decision for

placement of either PCN or JJ will be made based on evidence based arguments and in a uniform way. Hypothesis: Percutaneous nephrostomy is non inferior to retrograde double J catheter regarding time to clinical recovery. Secondly, patient reported outcome measures (PROMS) comparing treatment room and OR settings of drainage procedures will most likely not be significantly different. Finally, because percutaneous nephrostomy catheters are more often placed in a (outpatient) urological or radiological treatment room, this is expected to be less expensive than placement of a double J catheter (more often placed in the OR). Objective: To investigate the effectiveness of percutaneous nephrostomy catheter placement versus retrograde double J catheter placement in patients with symptoms of obstructive kidney disease (with either infection and/or pain and/or kidney function deterioration) caused by urolithiasis. Study design: Multicenter prospective randomized controlled non-inferiority trial. Study population: Male and female adult patients with signs of obstructive kidney disease with kidney or ureteral lithiasis as an underlying cause and with an indication for drainage based on symptoms of or laboratory tests indicating infection and/or pain and/or kidney function. Intervention: One group receives drainage by percutaneous nephrostomy catheter placement as opposed to the other group which will receive drainage by retrograde double J catheter placement. Main study parameters/endpoints: The primary objective is to assess whether a PCN is non-inferior to double J catheter regarding time to clinical recovery in patients with obstructive kidney disease resulting from urolithiasis. The primary outcome parameter is time to clinical recovery. Clinical recovery is defined as reaching one or more of the following criteria. The mandatory amount of criteria to achieve clinical recovery is dependent on the indication for placement of a PCN or a JJ. - If indication for drainage is infection: improvement of infection, indicated by a decrease of WBC in two executive laboratory results and below 15.000 mm3 and a body temperature of 36-38.5 C. and/or - If indication for drainage is untreatable pain: Numeric rating score (NRS) considering pain resulting from a renal colic is improved and < 3 points and/or - If indication for drainage is deterioration of kidney function: improvement of creatinine/ Glomerular Filtration Rate (GFR) in two executive laboratory results It may occur that the indication for drainage is a combination of the above named indications. Clinical recovery will then be reached in case all parameters related to the different indications are within the set range. Secondary outcomes are further clinical data, PROMS (measured by the EQ-5D-5L, NRS, a satisfaction scale and a catheter questionnaire) and societal costs (measured by a disease-specified iMCQ questionnaire). Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The placement of either PCN or double J catheter is standard care. Currently the choice for PCN or a double J catheter is based on expert opinion and may be driven by arguments considering logistics or assumptions about the quality of life for a patient after placement. Considering the difference in rate of placement of both PCN and double J catheter between various hospitals and different countries, it is believed experts have no uniform work method to handle the dilemma of choosing between these two techniques.[2] Furthermore the current EAU-guideline 2018 states that both methods of drainage are to be considered as equal.[1] Therefore there is no reason to believe, patients will be affected negatively by being placed randomly in either the double J group or the PCN group. Questionnaires will be filled in daily during hospitalization and twice or less afterwards. This is not considered to be a risk for the patient. The longest questionnaires (EQ-5D-5L and iMCQ) will take approximately 10-20 minutes to fill in, additional to the shorter scales (NRS, satisfaction scale) which will take approximately 1 minute to fill in. Generally It will take 90 minutes, spread over the course of three months, to fill in all questionnaires. For

frequency and timing of the questionnaires, see figure 1 under study procedure. Finally, no additional visits to a hospital, withdrawal of blood samples or exposure to radiation is to be expected when taking part in this study.

Study objective

Hypothesis: Percutaneous nephrostomy is non inferior to retrograde double J catheter regarding time to clinical recovery. Secondly, patient reported outcome measures (PROMS) comparing treatment room and OR settings of drainage procedures will most likely not be significantly different. Finally, because percutaneous nephrostomy catheters are more often placed in a (outpatient) urological or radiological treatment room, this is expected to be less expensive than placement of a double J catheter (more often placed in the OR).

Study design

3 months

Intervention

Placement of a nephrostomy versus placement of a double J catheter

Contacts

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Eligibility criteria

Age

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

Inclusion criteria

Inclusion criteria In order to be considered eligible to participate in this study, a subject must meet all of the following criteria: ● Male/female >18 year ● Symptoms and/or laboratory results indicating obstructive kidney disease with or without infection. ● A kidney or ureteral stone is present on ultrasound or CT (max 3 months old prior to presentation) ● Both drainage techniques are feasible and safe in opinion of the treating physician (from logistics point of view and in the best interest of the patient). ● Willing and able to comply with filling in questionnaires and follow-up regiment

Exclusion criteria

Exclusion criteria A potential subject who meets any of the following criteria will be excluded from participation in this study: ● Analphabetic or not mastering the Dutch language ● Pregnancy ● Usage of anticoagulation agents other than acetylsalicylic acid. ● Contraindication for either technique looking at history and anatomy (e.g. kidney transplant, pouch, Bricker deviation, urethral or ureteral stenosis)

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2020
Enrollment:	204
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO Date:	22-01-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 52865
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8128
CCMO	NL70822.058.19
OMON	NL-OMON52865

Study results