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Stent removal helps to spontaneously pass ureteral stones

Submission date	Recruitment status	[X] Prospectively registered
28/07/2019	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/08/2019	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/12/2024	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In some clinical situations patients with symptomatic ureteral stone disease patients are treated with double J stents before definitive stone treatment can be performed. Still, spontaneous stone passage is not uncommon after double J stent insertion. The question arises therefore whether secondary intervention is necessary at all as potential complications might thus be avoided. The aim of this trial is to assess whether removal of the double J stent can spare additional surgery and whether time point of removal (1 vs. 4 weeks) matters. Additionally, we try to distinguish which patients are optimal candidates for double J stent removal prior to secondary surgery and who should undergo surgery without prior stent removal

Who can participate?
Patients older than 18 years of age and who have received a double J stent due to a single ureteral stone. The ureteral stone needs to be radiopaque to facilitate detection of localization by X-ray

What does the study involve?
Before scheduled secondary intervention for stone extraction the patients will by assessed for spontaneous stone passage by patient interview and in case of no spontaneous stone passage radiological assessment (X-ray or low-dose computed tomography). In case of spontaneous stone passage the double J stent will be extracted by flexible cystoscopy and patients are discharged without the scheduled surgery. In case of stone persistence, the double J stent will be removed by flexible cystoscopy. If the stone passes within 24 hours the patients will be discharged without the scheduled secondary surgery. In case of stone persistence after double J stent removal the scheduled secondary surgery (ureteroscopy or SWL) will be performed for stone removal

What are the possible benefits and risks of participating?
Benefits:
Possible avoidance of secondary surgery for stone extraction.
Risks:
Possible unnecessary flexible cystoscopy in local anesthesia before secondary treatment in case of failure of spontaneous stone passage after double J stent removal. However, this represents

a minor intervention and the benefit of not having to undergo surgery outweighs the risk.
Possible renal colic after double J stent removal without prior stone passage. However, patient will be guarded in hospital and have immediate access to analgetics.
Possible urinary tract infection. However, patient will be administered an antibiotic prophylaxis to minimize this potential risk

Where is the study run from?
1. University Hospital Bern, Switzerland
2. CHUV Lausanne University Hospital, Switzerland

When is the study starting and how long is it expected to run for?
November 2019 to November 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Beat Roth
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KEK-Be 2017-01698

Study information

Scientific Title
A treatment strategy to help select patients who may not need secondary intervention to remove symptomatic ureteral stones after previous stenting

Acronym
NOSTENT

Study objectives
To evaluate whether removal of the ureteral stent the day before scheduled secondary intervention facilitates spontaneous ureteral stone passage and thus can spare the pre-stented patient this surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/11/2017, Ethical Committee of the Canton of Bern (Kantonale Ethikkommission für die Forschung, Murtenstrasse 31, 3010 Bern, Switzerland; +41 31 633 70 70; info.kek.kapa@gef.be.ch), ref: KEK-Be 2017-01698

Study design
Prospective randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Ureteral stone patients after previous stenting

Interventions

Methodology:
Patients presenting with a solitary, radiopaque, ureteral stone after double J stenting are eligible for participation. They will be randomized 1:1 for stent removal 1 vs. 4 weeks after stent placement.
Baseline diagnostics will be performed using non-contrast-enhanced computed tomography (NECT) in all patients. Stone size will be measured in three dimensions on axial and coronal images. Stone density will be measured using the bone window on the magnified axial NECT of the stone at maximal diameter. Before and/or during double J stent placement, conventional X-ray scan will be used to evaluate whether the stone is radiopaque. If the stone is radiolucent the patient will be excluded from further analysis. Patients are told to strictly filter their urine. Before discharge from hospital, patients will be randomized and secondary intervention is scheduled.
If no spontaneous stone passage is noted while the double J stent is in place, radiological assessment (X-ray or low-dose NECT) is performed the day prior to scheduled secondary intervention. Immediately thereafter, the double J stent is removed from all patients under local anesthesia using flexible cystoscopes in the outpatient clinic. A single shot of antibiotic prophylaxis (amoxicillin/clavulanate, ciprofloxacin or co-trimoxazole) is given at the time of stent removal. If spontaneous stone passage occurs, patients are discharged and followed up after 2 to 4 weeks by renal ultrasound for residual hydronephrosis. In the case of stone persistence, patients are hospitalized overnight and told to filter their urine. No additional medication (e.g. α-blockers, NSAID) will be given on a routine basis. Pain-induced additional use of analgesics (NSAID and metamizole as first choice; pethidine as second choice) and any other adverse events (e.g. urinary tract infection (UTI), renal colic) will be recorded. Spontaneous stone passage or persistence of the stone will be documented either by presenting the filtered stone and/or radiologically (X-ray or low-dose NECT) the following day. Secondary intervention will only be performed in case of persistence of the stone.
Total duration of treatment:
24h
Follow up:
Patients with spontaneous stone passage are followed up 2 to 4 weeks after double J stent removal for residual hydronephrosis.
Patients without spontaneous stone passage are followed up one day after double J stent removal and evaluated by radiological means (X-ray or low-dose NECT) and ultrasound for stone persistence. Secondary intervention (ureteroscopy or SWL) will then be followed the same day.
Randomization:
1:1 grouping by computer program

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Not provided at time of registration

Primary outcome measure

Ureteral stone-free rate at the time of and 24 hours after double J stent removal. As assessed by patient interview and/or radiological assessment.

Secondary outcome measures
Measured continuously throughout trial:
1. Predictors of spontaneous stone passage:
1.1 Stone size (diameter)
1.2 Stone location [proximal, mid- or distal ureter]
1.3 Stone density
1.4 Stent dwell time
1.5 Stone movement while stent indwelling. To assess stone movement, the dislocation of the stone from the initial spot immediately after double J placement was measured and compared to the X-ray pictures before stent removal. Because natural breathing movements of the patient can make evaluation of the exact stone location rather difficult, only stone movement of ≥5cm is measured and counted as stone movement.
1.6 Patient's age
1.7 Patient's gender
2. Adverse events:
2.1 Pain-induced additional use of analgesics
2.2 Urinary tract infection (UTI)

Overall study start date
01/11/2019

Completion date
01/11/2023

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Ureteral stone
2. Previous stenting
3. Stone still in place
4. Aged over 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
202

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/11/2019

Date of final enrolment
01/11/2023

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Bern
Freiburgstrasse
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Study participating centre
CHUV Lausanne University Hospital
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Sponsor information

Organisation
Inselspital, Universitätsspital Bern

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/01q9sj412

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Stone passage will be published in one of the 3 top journals of Urology; by the end of 2023

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date