Placement of a double-J catheter transurethral via the urinary bladder versus transcutaneous via the kidney in patients with extrinsic obstruction of the ureter.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25446

Source
NTR

Brief title
RAPPER trial

Health condition

Extrinsieke ureter obstructie
Extrinsic ureter obstruction

Sponsors and support

Primary sponsor: Dr. H. van Overhagen
Haga Ziekenhuis
Leyweg 275
2545 CH Den Haag
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Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

Immediate technical success rate

Secondary outcome

• To compare VAS scores after retrograde and antegrade stent insertion in patients with extrinsic urinary tract obstruction.
• To compare the complications after retrograde and antegrade stent insertion in patients with extrinsic urinary tract obstruction.
• To compare technical success rates at 30 days after retrograde and antegrade stent insertion in patients with extrinsic urinary tract obstruction.
• To compare scores on EQ5D questionnaire at 30 days after retrograde and antegrade stent insertion in patients with extrinsic urinary tract obstruction.
• To assess possible predictive factors for immediate technical success.
• To assess possible predictive factors for technical success at 30 days.
• To assess possible predictive factors for the evolvement of major and minor complications.
• To assess possible predictive factors for the outcome on the EQ5D questionnaire.

Study description

Study design

• Intervention
• 7 days after intervention
• 30 days after intervention

Intervention

• Retrograde placement of a double-J catheter
• Antegrade placemnet of a double-J catheter

Contacts

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Eligibility criteria

Inclusion criteria

• Legally capable and written informed consent
• 18 years or older
• A CT or MRI diagnosis of extrinsic ureter obstruction by visible or non-visible mass surrounding the urinary tract
• Possible dorsal percutaneous approach to kidney
• Possible transvesical approach
• Possible treatment by an urologist and intervention radiologist with sufficient experience
• Patient is willing and able to comply with the specified follow-up evaluation

Exclusion criteria

• Active infection, defined as temperature >38,0 °C
• Macroscopic haematuria
• INR > 2,0
• Thrombocytes < 50 109/l
• Ileal conduit urinary diversion
• Kidney transplantation
• Horseshoe kidney
• Known allergy to contrast media

• Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	214
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-11-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42126
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4786
NTR-old	NTR4925
CCMO	NL49696.098.14
OMON	NL-OMON42126

Study results