

Retrograde versus antegrade placement of a double-J catheter in patients with extrinsic ureter obstruction

Published: 19-11-2014

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The purpose of this study is to compare the technical success rates, scores on the visual analogue scale (VAS) and complications after retrograde and antegrade double J catheter insertion in patients with extrinsic urinary tract obstruction.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON42126

Source

ToetsingOnline

Brief title

RAPPER - trial

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Ureteric disorders
- Renal and urinary tract therapeutic procedures

Synonym

blockage of the kidney drainage tube, Extrinsic ureteral obstruction

Research involving

Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

Source(s) of monetary or material Support: Onderzoeksgelden afdeling Radiologie
HagaZiekenhuis

Intervention

Keyword: Antegrade, Double-J catheter, Retrograde, Ureteral obstruction

Outcome measures

Primary outcome

The primary endpoint is the immediate technical success rate.

Secondary outcome

Secondary study endpoints are VAS score immediately after the procedure, technical success rate at 30 days, mortality within 30 days, major complications (i.e. transfusion required retroperitoneal bleeding, perforation, sepsis) and minor complications (i.e. urinary tract infection, macroscopic haematuria, inflammation of the skin) within 30 days, renal function at 7 days and 30 days and score on the EQ5D questionnaire at 30 days after intervention.

Study description

Background summary

Percutaneous nephrostomy is common treatment for acute hydronephrosis. However, the external catheter shows a high incidence of complications in long-term management, such as infection and dislocation. For the long-term treatment of ureter obstruction an internal nephro-ureteral catheter can be used (double J catheter). These catheters are generally inserted by a retrograde approach under cystoscopic guidance, often under general anaesthesia. Insertion however may be difficult, or in some cases even impossible. The alternative is then insertion through percutaneous access in an antegrade fashion.

Study objective

The purpose of this study is to compare the technical success rates, scores on the visual analogue scale (VAS) and complications after retrograde and antegrade double J catheter insertion in patients with extrinsic urinary tract obstruction.

Study design

Randomized controlled trial.

Intervention

Subjects will be randomized to receive a double J catheter inserted by a retrograde or an antegrade approach.

Study burden and risks

Participating subjects will be asked to give a VAS score direct after treatment. 30 days after treatment subjects will be asked to fill in a questionnaire (the EQ5D).

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

CT or MR diagnosis of extrinsic ureter obstruction

Exclusion criteria

Active infection (temperature $>38^{\circ}\text{C}$)

Macroscopic haematuria

INR $> 2,0$ or Thrombocytes $< 50\ 109/l$

Ileal conduit urinary diversion

Kidney transplantation

Known allergy to contrast media

Pregnancy

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-03-2016

Enrollment: 214

Type: Actual

Ethics review

Approved WMO

Date: 19-11-2014

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO

Date: 24-11-2015

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO

Date: 12-12-2016

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Not approved

Date: 18-01-2018

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO

Date: 09-04-2018

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25446

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL49696.098.14
OMON	NL-OMON25446