Omission of stent placement on ileal urinary conduit

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To assess whether the omission of IOS placement in patients undergoing cystectomy and ileal urinary conduit results in a similar per patient event-free 30-day survival rate as compared to those who receive regular IOS placement.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal and urinary tract therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON51093

Source
ToetsingOnline

Brief title
NO-STENTS trial

Condition

- Renal and urinary tract therapeutic procedures

Synonym
Urinary deviation

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Blaaskanker studie;DUOS grant

Intervention

Keyword: Cystectomy, Ileal urinary conduit, Stent, Urinary diversion

Outcome measures

Primary outcome

The primary endpoint is the UIA associated complication rate within 30 days postoperatively. This is a composite endpoint of the following complications:

1) Radiological or biochemical evidence of urinary tract leakage at the UIA defined as contract extravasation on computer tomography (CT) of the abdomen or elevated levels of creatinine in the fluid of the wound drain from the second day postoperatively and onwards,

2) Ureteral stricture or obstruction

Abovementioned complications should require substantial prolonging of the wound drain, placement of a percutaneous drain in a urinoma, placement of a nephrostomy tube or secondary intervention.

3) Evidence/suggestion of upper urinary tract infection defined as a positive urine culture with symptoms such as of fever (T >= 38.5°C) , chills, groin pain, and/or elevation of inflammation parameters, which requires antibiotic treatment. Or evidence/suggestion of urinary tract sepsis defined as a positive urine and blood culture, with identical cultures

Secondary outcome

- The 90 days postoperatively complication rate which is a composite endpoint

of the complications mentioned in the primary endpoint,

- Total days of hospital admission and re-admittance from day of surgery till

30 days postoperatively

- Loss of kidney function > 20 ml/min at approximately 1 year postoperatively

- The frequency of uretero-ileo anastomotic strictures at approximately 1 year

postoperatively requiring secondary drainage or intervention

Study description

Background summary

Scientific evidence for the hypothesis that intra-operative ureteric stent (IOS) placement on ileal urinary conduit improves the alignment of the uretero-ileal anastomosis is lacking. Current literature even suggests that the omission of IOS placement would result in a decrease of the incidence of urinary tract related complications.

Study objective

To assess whether the omission of IOS placement in patients undergoing cystectomy and ileal urinary conduit results in a similar per patient event-free 30-day survival rate as compared to those who receive regular IOS placement.

Study design

A multicenter, prospective randomized clinical trial

Intervention

Patients who are scheduled for ileal urinary conduit with or without cystectomy are screened for eligibility and are asked to participate. After 1:1 randomization, 192 patients receive either routine IOS placement (standard of care), or no IOS placement (study group

Study burden and risks

No extra site visits are needed. Regular care is performed in all patients,

also when treatment of complications is concerned. It is assumed that patients in the study group have similar outcomes in the SOC group with respect to the primary (and secondary) outcome variables. Though, there might be small chance that patients in the study group do worse with respect to the incidence of complications.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1007MB
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1007MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- 18 years and older
- Able to understand patient information form (PIF),
- Written informed consent, on study participation
- Undergoing open or robot-assisted uretero-ileo-cutaneostomy with or without radical cystectomy for urothelial cell carcinoma or other pelvic malignancies,

refractory urinary incontinence or refractory detrusor overactivity
- eGFR >= 30 ml/min

Exclusion criteria

- Neobladder or any reconstruction other than uretero-ileo-cutaneostomy of the urinary tract
- Open uretero-ileo-cutaneostomy
- Pre-operative obstruction of the upper urinary tract requiring a nephrostomy catheter or double-J stent
- Single-functioning kidney
- Previous radiation therapy of the lower pelvis, except for prostate cancer
- Salvage Cystectomy
- History of colorectal surgery, or M. Crohn/colitis ulcerosa or short bowel syndrome

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-12-2021
Enrollment:	192
Type:	Actual

Ethics review

Approved WMO Date:	22-09-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL76874.029.21