Validation of 2 BladderScans for measuring bladder volume non-invasively.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26134

Source
Nationaal Trial Register

Health condition

Measuring bladder volume perioperatively is necessary to prevent uneccessary urinary catheterization but it is even more important in preventing Post Operative Urinary Retention and bladder distention.

In het voorkomen van onnodige blaascatheterisatie en blaasoverrekking door een te volle blaas na de operatie is een juiste meting van de blaasinhoud zeer belanrijk. in dit onderzoek kijken we of de nieuwe BladderScan PRIME die ook met echte echobeelden kan werken nauwkeuriger is in het meten van de blaasinhoud dan de oudere versie van de BladderScan de BVI 9400

Sponsors and support

Primary sponsor: Medical Centre Leeuwarden
Source(s) of monetary or material Support: Verathon Inc, 20001 North Creek Pkway, Bothell, WA 98011, Verenigde Staten van Amerika

Intervention

Outcome measures

Primary outcome

The difference plus standard deviaton in volume in ml between the measured bladder volumes with the BladderScans, using the three different measuring methods, and the measured the urine volume retrieved after urinary.catheterization. Comparing 3 groups of 100 patients for each measurement type; first 100 patients with the BVI 9400, followed by 100 patients measured with the PRIME without pre-scan and than 100 patients measured with the PRIME using pre-scan.

Secondary outcome

The difference in volume in ml between the measured bladder volume with the BladderScan and the measured urine volume after catheterization over the small to large urine volume ranges; i.e. quartiles of the measured urine volume after catheterization. Next to this, other possible relevant patient factors may influence the results and will be analyzed e.g. gender, age and BMI.

Study description

Background summary

It is important to know the perioperative bladder volumes of surgical patients to prevent not only unnecessary bladder catheterizations but also to prevent bladder over distention. Non-invasive bladder volume measurement is possible, but how acurate are these devices in clinical practice and is the new PRIME, with new software and the possibility to pre-scan the bladder using real time echo images, more accurate than the its precessor the BVI 9400? We will found out.

Study objective

The newer BladderScan PRIME with real time echo images (= pre-scan) is more accurate in measuring bladder volumes than measuring bladder volume without pre-scan or than the older version of the BladddderScan; the BVI 9400. and

Study design

To include 100 patients per each BladderScan will take about 5 tot 6 weeks .

Intervention

Bringing in urinary catheters following the clinical protocols used in the MCL

Contacts

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Eligibility criteria

Inclusion criteria

Adult patients (> 18 Y) who will be operated in the Medical Centre Leeuwarden needing a urinary catheter perioperatively and postoperative patients with a measured bladder volume larger than 500 ml and inability to void spontaneously provided written informed consent

Exclusion criteria

Patients who have a suprapubic incision making the measurement impossible

Pregnancy

Patients with ascites

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-06-2016
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-08-2016
Application type:	First submission

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
NTR-new	NL5884

Register	ID
NTR-old	NTR6057
Other	nWMO 132 : RTPO 965

Study results

Summary results

Brouwer TA, Eindhoven BG, Epema AH, Henning RH. Validation of an Ultrasound Scanner for Determing Urinary Volumes in Surgical Patients and Volunteers. J Clin Monit Comput; 1999, 15(6), 379-385.
Brouwer TA. Retenton d'Urine et Anomalies de la Miction en Postoperatoire. Le Practicien en Anesthesie reanimation. 2003; 7(2), 129-135.
Keita H, Diouf E, Tubach F, Brouwer T, Dahmani S, Mantz J, Desmonts JM. Predictive Factors of early Postoperative Urinary Retention in the Postanesthesia Care Unit. Anest.Analg. 2005; 101(2), 592-596.
Brouwer TA, Rosier PFWM, Moons KGM, Zuithoff NPA, Roon EN Kalkman CJ. Postoperative Bladder Catheterization Based on Individual Bladder Capacity: A Randomized Trial. Anesthesiology. 2015, 122(1), 46-54.