Low pressure pneumoperitoneum during laparoscopic donornephrectomy: a pilot study

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The feasability of a randomized trial studying the advantageous effects of low-pressure pneumoperitoneum during laparoscopic donornephrectomy will be assessed.

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

Summary

ID

NL-OMON36005

Source
ToetsingOnline

Brief title
LEOPARD study

Condition

- Renal and urinary tract therapeutic procedures

Synonym
postoperative pain, renal injury

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Donornephrectomy, Kidney, Laparoscopy, Pneumoperitoneum

Outcome measures

Primary outcome

Postoperative pain (numeric rating scale).

Secondary outcome

Nauseascore, postoperative hyperalgesia (QST), cumulative use of painmedictation, cardiopulmonal effects during the operation, lenght of hospitalisation, quality of life, return to work and function of the remaining kidney of the donor.

Study description

Background summary

Living donor kidney donation is currently the most effective strategy to manage the shortage of donor kidneys. In this way mortality of patients with end-stage renal disease is reduced and the waitinglist for transplantation shortened. Furthermore it is possible to transplant prior to initiation of dialysis. This prevents other interventions (for example shunt surgery) required for dialysis. The last years the number of kidneys from unrelated donors is increasing. The willingness among friends or even anomynous individuals to donate is increasing. Evidently the ethical basis for living donor kidney donation is shifting. With a decreasing connection between donor and recipient, it becomes less clear what the win is for the donor in daily life. In this context it is essential that surgical techniques are optimised and that safety of the donor is garantueed as much as possible. In previous studies it has been shown that donor benefit from kidney donation using a laparoscopic technique. Compared with a minimal invasive, open technique, laparoscopic kidney donation correlates with a better quality of life, less pain, shorter hospitalization and earlier return to work.
For further optimization of the technique of laparoscopic kidney donation, the procedure could be performed using low pressure for the insufflation of carbonic gas in the abdominal cavity (pneumoperitoneum). In the current practive standard pressures between 12 and 14 mmHg are used, however from

literature it is known that laparoscopic operations can be performed in a safe manner with pressures between 7 and 9 mmHg. In patients undergoing laparoscopic operations, low pressure pneumoperitoneum reduces the incidence of referred shoulder pain, postoperative painscores and the use of opiates. Furthermore there are clear indications that conventional pressure pneumoperitoneum reduces the perfusion of abdominal organs and could lead to a temporary reduction in renal function.It is not known whether this has consequences for renal function in the long-term. Since it is of great importance to reduce the risk for kidney donors as much as possible, the technique of low pressure pneumoperitoneum during laparoscopic donornephrectomy is simple, safe and low-cost.

Hypothesis: the use of low pressure pneumoperitoneum during laparoscopic donornephrectomy leads to reduced postoperative painscores, opiate use, improved quality of life, earlier return to work and preservation of renal function of the remaing kidney in the donor.

Study objective

The feasability of a randomized trial studying the advantageous effects of low-pressure pneumoperitoneum during laparoscopic donornephrectomy will be assessed.

Study design

A single-centre, double blind, randomized pilot-study wil be performed. Randomization will occur after intubation and positioning of the patient on the operating table by a research assistant. A computer generated randomizationlist will be used. Twenty patients will be included and randomized in two groups; conventional pressure versus low-pressure pnuemoperitoneum during laparoscopic donornephrectomy. The technique (conventional or low-pressure) will not be communicated to the patient until the last questionaires are completed 3 months postoperative. Follow-up including urine samples, QST-measurements and quality of life and return to work forms will done until 3 months after the operation.

Intervention

Laparoscopic donornephrectomy will be performed in a standard manner. A research assistant will set the pressure for inflation of the abdominal cavity after placement of the first trocar at 7 or 14 mmHg depending on randomisation. After placement of the first subcostal 5 mm trocar a infusion catheter (sterile) is connected to this port. The infusion catheter (filled with air) is connected to an IBP (invasive blood pressure) sensor wich is connected to the artery catheter channel of the patientmonitor. Continuously measured intra-abominal pressure is made invisible at the patientmonitor for the surgeon and all personell present at the operating room. In case of a significant bleeding during the operation (>100 ml blood loss) or in case of insufficient

exposure of the operating field limiting progress of the procedure (determined by the surgeons; urologist and vascular surgeon), blinding is abrogated and the pressure will be converted to standard (if applicable).

Study burden and risks

Burden:
In total 17 questionnaires should be completed (3x preoperative, 14x postoperative). To take a blood sample and a fresh urine sample at postoperative day 7 patients should visit the outpatient clinic once (1 week after the operation) beside to the scheduled routine visits to the outpatient clinic. Furthermore a specially trained research-nurse will perform 3 QST measurements (pre-operative and postoperative at day 1 and 3) during hospital stay in a quiet room at the nursing department. The fourth and last QST measurement will be performed during a routine visit at the outpatient clinic after 3 months.

Risks:
It is expected that lowering the pressure of the pneumoperitoneum has no effect on: duration of the operation, blood loss, chance of conversion to an open procedure (laparotomy) or rare complications (such as bowel injury). In the existing literature none of the abovementioned adverse effects are found to occur more frequent in those patients undergoing low-pressure pneumoperitoneum procedures. To garantee the safety of the participants of this study as much as possible, conversion to standard pressure (after unblinding) will be performed in cases of a significant bleeding (>100 ml) or insufficient exposure of the operating field. If an unexpected, severe (rare) complication occurs in one of the participant (e.g. bowel- or pancreatic injury, re-intervention due to bleeding) unblinding will be effectuated and a possible causal relationship with low-pressure pneumoperitoneum will be assessed. If the team of researchers (2 urologists, 2 nephrologists and 3 vascular surgeons) conclude that the complication is possibly related to low-pressure pneumoperitoneum, then further inclusion of patients will be stopped.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Participants in this study should be eligible for kidney donation and have sufficient understanding of the Dutch language to complete the quality of life and return to work forms. Informed consent is required.

Exclusion criteria

Donors with previous renal- or adrenal surgery at the ipsilateral side or not eligible.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	31-05-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL36430.091.11