A randomized controlled trial comparing deep versus moderate neuromuscular block - in low pressure pneumoperitoneum - to optimize the surgical conditions during laparoscopic donor nephrectomy

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To investigate whether the use of deep neuromuscular block improves surgical conditions in low pressure laparoscopic donor nephrectomy

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON40989

Source
ToetsingOnline

Brief title
LEOPARD-3 study

Condition

- Renal disorders (excl nephropathies)
- Renal and urinary tract therapeutic procedures

Synonym
donor nephrectomy, kidney donation

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: deep neuromuscular block, laparoscopic donor nephrectomy, low pressure pneumoperitoneum, surgical conditions

Outcome measures

Primary outcome

Mean surgical rating score

Secondary outcome

Questionnaires

• Quality of recovery-40 questionnaire

Medication use

• Cumulative use of analgetics

• Cumulative use of anti-emetics

Intra-operative parameters

• Operation time (min), length of pneuoperitoneum (min), first warm ischemia

time (sec)

• Estimated blood loss (ml)

• Conversion to open donor nephrectomy (incidence)

• Conversion to hand-assisted donor nephrectomy (incidence)

• Intra-operative complications (e.g. bleeding, injury to spleen or liver)

• Cumulative use of rocuronium (mg)

• Cumulative use of sugammadex (mg)

• Intra-abdominal volume (mL)

Clinical parameters

• Components of pain assessment

• Evaluation of post-operative complications, graded according to Clavien Dindo

• Post-operative incidence of nausea and/or vomiting

• Serum creatinine

Study description

Background summary

As both patients with end-stage kidney disease and society benefit tremendously from live kidney donation, the safety and well-being of kidney donors are highly important objectives in live kidney donation. Laparoscopic donor nephrectomy has several advantages over open donor nephrectomy, such as less post-operative pain, better quality of life and shorter hospital stay1. Therefore, laparoscopic donor nephrectomy is nowadays the treatment of choice. So far, modifications of the technique of laparoscopic donor nephrectomy, i.e. hand-assisted and/or retroperitoneoscopic approaches, did not show a significant benefit with regard to safety as reflected by the conversion to open and postoperative complication rate2-4. We therefore believe that further research should focus on the optimization of early postoperative recovery. Postoperative recovery is largely determined by the consequences of postoperative pain and its concomitant use of opioids. Measures to reduce postoperative pain would also reduce the occurrence of postoperative drowsiness, nausea and vomitus, and postoperative bowel dysfunction. Pain after laparoscopic surgery can be divided into three components: a) superficial wound pain, b) deep intra-abdominal pain and c) referred shoulder pain5. A recent pilot study performed by our group (Radboudumc) showed that the use of low pressure pneumoperitoneum (7 mmHg) was feasible and significantly reduced deep intra-abdominal and referred pain scores during the first 72 hours after surgery6. Previous studies by others show that low pressure pneumoperitoneum during laparoscopic Nissen fundoplication and laparoscopic

cholecystectomy is associated with a reduction of the systemic inflammatory response, less adverse impact on the peritoneal environment, post-operative pain and analgesic consumption7-10. However, low pressure pneumoperitoneum can decrease peri-operative conditions. A recent study performed by our group (LUMC) showed that profound muscle relaxation improves surgical conditions during laparoscopic surgery with standard pressure pneumoperitoneum11. To facilitate the use of low pressure pneumoperitoneum, profound muscle relaxation -in theory- improves surgical conditions and might become a prerequisite for the use of low pressure pneumoperitoneum.

Study objective

To investigate whether the use of deep neuromuscular block improves surgical conditions in low pressure laparoscopic donor nephrectomy

Study design

multi-center, single-blind, randomized, controlled clinical trial

Intervention

The patient will be randomized in one the following study groups:
• Low pressure pneumoperitoneum (6 mmHg) and deep neuromuscular blockade (goal: TOF 0-1 twitches)
• Low pressure pneumoperitoneum (6 mmHg) and moderate neuromuscular blockade (goal: PTC 0-5)

Study burden and risks

The patient will be asked to fill in some questionnaires:
• Quality of recovery-40: 3x 5 minutes = 15 minutes
• Components of pain assessment: 3x 2 minutes = 6 minutes
• Nausea score = 3x 1 minute = 3 minutes

Total estimated less than 30 minutes

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

obtained informed consent
age >18 years

Exclusion criteria

• chronic use of analgetics or psychotropic drugs
• use of NSAIDs shorter than 5 days before surgery
• known of suspect allergy to rocuronium or sugammadex
• significant liver* or renal** dysfunction
• pregnant of breastfeeding;* Liver dysfunction is defined as alanine aminotransferase (ALAT) and/or aspartate aminotransferase (ASAT) > twice the upper limit (extremely rare in live kidney donors)
** Renal dysfunction is defined as serum creatinine twice the normal level and/or glomerular filtration rate < 60 ml/min (extremely rare in live kidney donors)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-08-2014
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	10-11-2014
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	NL50874.091.14