The effectiveness of deep versus moderate neuromuscular blockade during laparoscopic donor nephrectomy in enhancing postoperative recovery.

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To establish the relationship between the use of deep neuromuscular blockade (NMB) during laparoscopic donor nephrectomy (LDN) -with standard pressure pneumoperitoneum- and the early quality of recovery.

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

Summary

ID

NL-OMON42929

Source
ToetsingOnline

Brief title
RELAX-study

Condition

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

Synonym
kidney donation, living donor nephrectomy

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: MSD

Intervention

Keyword: Deep neuromuscular blockade, Laparoscopic donornephrectomy, Postoperative recovery

Outcome measures

Primary outcome

The quality of Recovery score (QoR-40 questionnaire) at 24 hours after

extubation

Secondary outcome

* Quality of recovery-40 score at 48 hours after extubation (appendix 1)

Medication use:

* Cumulative opiate use

* Cumulative use of other analgesics and anti-emetics

Intra-operative parameters:

* Surgical conditions; the Surgical Rating Scale is used to quantify the

quality of the surgical field during the pneumoperitoneum phase (after

introduction of the Hasson trocar, after introduction of all trocars and then

every 15 minutes).

* Intra-operative complications (e.g.major bleeding, spleen or liver injury)

* Operation time, length of pneumoperitoneum, first warm ischemia time

* Estimated blood loss

* Conversion to open donor nephrectomy

* Conversion to hand-assisted donor nephrectomy

Clinical parameters:

* Components of pain scores (NRS 0-10):

* Superficial wound pain score at 1, 4, 8 24, 48 hours (after extubation)

* Deep intra-abdominal pain score at 1, 4, 8, 24, 48 hours

* Referred shoulder pain score at 1, 4, 8, 24, 48 hours

* Post-operative nausea and/or vomiting (NRS)

* Time to reach discharge criteria*

Follow up:

* Complications up to 30 days after surgery

* Pain scores 4 weeks afters surgery

* Questionnaire about work and need for medical care

* discharge criteria are: adequate pain control with oral medication, passage of flatus or defecation, intake of solid food tolerated, patient is mobilized and independent and patient accepts discharge. Discharge criteria will be evaluated daily. If the donor for social reasons wants to stay longer (e.g. long distance from partner of child who are still hospitalized) the *virtual* discharge date is listed. A physician who is independent and blinded (ward

physician) is responsible for the actual discharge date.

Study description

Background summary

Live kidney donation is currently the most effective strategy to manage the shortage of donor kidneys for transplantation. The increased use of living donors will decrease the number of patients on the waiting list and this subsequently reduces mortality of these patients.
Therefore, efforts to optimize safety and postoperative recovery are of great importance.
Based on the outcomes of previous studies of our group, we hypothesize that the use of deep NMB during LDN -with standard pressure PNP- enhances early postoperative recovery as compared to moderate NMB.

Study objective

To establish the relationship between the use of deep neuromuscular blockade (NMB) during laparoscopic donor nephrectomy (LDN) -with standard pressure pneumoperitoneum- and the early quality of recovery.

Study design

a multicenter, blinded, randomized controlled trial

Intervention

The patient will be randomized in one of the following study groups:
- deep neuromuscular blockade
- moderate neuromuscular blockade

Study burden and risks

Negligible risk, with a small chance of minimal harm.
The extended effects of deep neuromuscular blockade can lead to post-operative complications, such as airway obstruction, hypoxia, pneumonia and/or atelectasis. Therefore, sugammadex, a rapid antagonist of neuromuscular blockade is given immediately after surgery. Randomized controlled trials have shown that sugammadex can be safely administered in patients.

Participation is just a small burden for the patients, The questionnaires cost the patients approximately ten minutes a day.

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

- individuals scheduled for living kidney donation
- age over 18 years
- obtained informed consent

Exclusion criteria

- insufficient control of the Dutch language to read the patient information and to fill out the questionnaires
- chronic use of analgesics or psychotropic drugs
- use of NSAIDs shorter than 5 days before surgery
- known or suspect allergy to rocuronium of sugammadex

- neuromuscular disease
- indication for rapid sequence induction
- deficiency of vitamin K-dependent clotting factors, coagulopathy or use ofcoumarin derivates.
- Peri-operative use of fusidic acid or flucloxacilline
- Severe renal impairment (creatinine clearance <30ml/min)

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2016
Enrollment:	96
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bridion
Generic name:	Sugammadex
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Esmeron
Generic name:	Rocuronium
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	08-08-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-10-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-02-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-03-2017
Application type:	Amendment
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
EudraCT	EUCTR2016-002924-99-NL
CCMO	NL58160.091.16