

# Effect of deep versus moderate neuromuscular block during sevoflurane anesthesia on intraoperative surgical conditions, hemodynamics and postoperative pain in patients undergoing laparoscopic surgery for (donor) nephrectomy \*

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Main objective To study the surgical conditions in patients undergoing laparoscopic renal or prostate surgery during deep versus moderate neuromuscular block as assessed by the Leiden Surgical Rating Scale.Minor objectives1. To study the hemodynamic...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON48952

### Source

ToetsingOnline

### Brief title

BLISS 4

### Condition

- Other condition

### Synonym

anesthesia, narcosis

## Health condition

anesthesie voor urologische laparoscopische ingrepen

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W, MSD

## Intervention

**Keyword:** anesthesia, neuromuscular block, relaxation, surgical rating

## Outcome measures

### Primary outcome

The main end-point of the study is the effect of the deep block on surgical conditions during sevoflurane anesthesia. To that end-the surgical team will be asked to rate the quality of the surgical field at 15-min intervals using the 5-point Leiden-Surgical Rating Scale (L-SRS), a scale that was previously developed at LUMC and recently validated

### Secondary outcome

Secondary end-points of the study are hemodynamics (blood pressure and heart rate) and Nociception Level (NoL [3]) during anesthesia, and pain and sedation scores following surgery.

## Study description

### Background summary

In two independent studies we previously showed that deep NMB produces superior surgical rating scores compared to a moderate NMB [1,2]. In retroperitoneal

surgery, for example, we showed that during propofol anesthesia deep NMB was associated with a mean surgical rating scale (SRS) of 4.7 (on a 5-point scale) compared to a score of 4.0 during moderate NMB. This difference was considered highly significant by the surgeon. Since both studies were performed during general anesthesia with the intravenous anesthetic propofol, it remains unknown what the influence is of the anesthesia type on the SRS scores. Therefore we will now study the effect of deep versus moderate NMB on SRS scores during sevoflurane in retroperitoneal surgery. We expect a difference in SRS scores albeit of smaller magnitude than in our first two studies since sevoflurane has neuromuscular relaxing properties.

1. Martini M, Boon M, Bevers R, Aarts L, Dahan A. Evaluation of surgical conditions during laparoscopic surgery in patients with moderate versus deep neuromuscular blockade. *Br J Anaesth* 2014; 112: 498-505
2. Torensma B, Martini C, Boon M, Olofsen E, in 't Veld B, Liem RSL, Knook MTT, Swank DJ, Dahan A. Deep neuromuscular block improves surgical conditions during bariatric surgery and reduces postoperative pain: a randomized double blind controlled trial. *PLoS ONE* 2016; 11: 20167907

## **Study objective**

### **Main objective**

To study the surgical conditions in patients undergoing laparoscopic renal or prostate surgery during deep versus moderate neuromuscular block as assessed by the Leiden Surgical Rating Scale.

### **Minor objectives**

1. To study the hemodynamic conditions during deep versus moderate neuromuscular block.
2. To study the nociception level during deep versus moderate neuromuscular block.
3. To assess the effect of deep versus moderate NMB on pain, sedation and nausea/vomiting in the recovery room (PACU).
4. To compare rating of the surgical field obtain from video images among surgeons and anesthesiologists.

## **Study design**

Double-blind randomized

## **Study burden and risks**

None to be expected

## Contacts

### Public

Leids Universitair Medisch Centrum

Albinusdreef 2  
Leiden 2333 ZA  
NL

### Scientific

Leids Universitair Medisch Centrum

Albinusdreef 2  
Leiden 2333 ZA  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- (i) Patients diagnosed who are will undergo an elective laparoscopic renal surgical procedure, i.e. (donor) nephrectomy
- (ii) ASA class I-III
- (iii) > 18 years of age;
- (iv) Ability to give oral and written informed consent.

### Exclusion criteria

- (i) Known or suspected neuromuscular disorders impairing neuromuscular function;
- (ii) Allergies to muscle relaxants, anesthetics or narcotics;
- (iii) A (family) history of malignant hyperthermia;

- (iv) Women who are or may be pregnant or are currently breast feeding;
- (v) Renal insufficiency, as defined by serum creatinine x 2 of normal, or urine output < 0.5 ml/kg/h for at least 6 h. When available, other indices will be taken into account as well such as glomerular filtration rate < 60 ml/h and proteinuria (a ratio of 30 mg albumin to 1 g of creatinine).
- (vi) Previous retroperitoneal surgery at the site of the current surgery.
- (vii) Body mass index > 35 kg/m<sup>2</sup>

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2018
Enrollment:	100
Type:	Actual

## Ethics review

Approved WMO	
Date:	20-04-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date: 06-09-2018  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO  
Date: 13-09-2019  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

## 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	NL60821.058.17