The BLISS 4 trial

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23555

Source
NTR

Brief title
BLISS4

Health condition

not applicable, mostly healthy individuals

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: MSD

Intervention

Outcome measures

Primary outcome

Leiden Surgical rating score

Secondary outcome

Hemodynamic conditions
Postoperative recovery and pain

Peroperative NOL values

Study description

Background summary

To assess whether a deep neuromuscular block provides better surgical conditions (L-SRS) than a moderately deep block as derived from a surgical rating score during sevoflurane anesthesia.

Study objective

The difference in surgical conditions between deep or moderate neuromuscular block is absent during sevoflurane anesthesia

Study design

N.A.

Intervention

deep neuromusculair block vs moderate neuromusculair block

Contacts

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Eligibility criteria

Inclusion criteria

(i) Patients that will undergo an elective laparoscopic (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/m2

Study design

Design

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

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-06-2019
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	NL7844
Other	METC LUMC : P17.049

Study results