The impact of deep versus standard muscle relaxation on intra-operative safety during laparoscopic surgery: a multicenter strategy study

Published: 08-10-2019
Last updated: 10-04-2024

To study the effect of deep neuromuscular block compared to standard neuromuscular block on intra-operative adverse events during laparoscopic surgery using the CLASSIC score system.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON52488

Source
ToetsingOnline

Brief title
EURO RELAX

Condition

- Other condition

Synonym
anesthesia, narcosis

Health condition

anesthesia during laparoscopic surgery i.e. upper gastrointestinal, lower gastrointestinal, urological and gynecological

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Merck

Intervention

Keyword: anesthesia, complications, laparoscopic surgery, neuromuscular block

Outcome measures

Primary outcome

Primary Objectives:

To study the effect of deep neuromuscular block compared to standard

neuromuscular block on intra-operative adverse events during laparoscopic

surgery using the CLASSIC score system;

Secondary outcome

To study the effect of deep neuromuscular block as compared to standard

neuromuscular block on:

• Surgical working conditions (L-SRS)

• 30 day post-operative complications (Clavien-Dindo,)

• 30-day post-operative complications according to the Comprehensive

Complication Index (https://www.assessurgery.com/)

• 30 day unplanned readmission rates

• Quality of recovery at post-operative day 1 and 2 after laparoscopic

surgery.(QoR 40)

• Quality-of-life at postoperative day 30 (SF36)

Study description

Background summary

Muscle relaxants are routinely applied during anesthesia to facilitate endotracheal intubation and to improve surgical working conditions. Several investigations have shown that a deep neuromuscular block (NMB) (post tetanic count (PTC) 1-2 twitches) improves the surgical working conditions over a moderate NMB (TOF count 1-3 twitches) and effectively precludes sudden deterioration of the surgical field. However, whether the improvement of surgical working conditions translates into less intra- and postoperative complications remains uncertain. A recent retrospective analysis of neuromuscular management during laparoscopic retroperitoneal surgery showed a reduced rate of unplanned 30 day readmissions when a deep NMB over a moderate NMB was applied (3.8% vs. 12.7%).In addition, a pooled analysis of 4 randomized controlled trials comparing different levels of intra-abdominal pressure and neuromuscular blockade during laparoscopic donor nephrectomy, showed a significant reduction in the incidence of intra-operative surgical complications from 12.6% with moderate NMB to 4.8% with deep NMB.

These previous observations were made in small prospective or retrospective studies. There is a need to confirm these outcome data prospectively, in a larger prospective trial for a variety of surgical procedures. We therefore propose a multi-center, randomized controlled trial, to study the effect of a deep NMB (PTC 1-2 twitches) versus standard NMB (single induction dose rocuronium) in a variety of laparoscopic surgical procedures on the incidence of intraoperative adverse events and postoperative outcome data.

Study objective

To study the effect of deep neuromuscular block compared to standard neuromuscular block on intra-operative adverse events during laparoscopic surgery using the CLASSIC score system.

Study design

The EURO Relax is an investigator initiated, multi-center, randomized controlled trial in patients undergoing laparoscopic abdominal surgery. A multicenter design was chosen to optimize generalizability and to guarantee patient enrollment within 14-15 months. Patients undergoing laparoscopic surgery in different fields of surgery will be randomized 1:1 in blocks of 2 and 4 to the deep or standard neuromuscular block group. Randomization will be stratified per center and BUPA category (MAJOR, MAJOR PLUS or COMPLEX MAJOR).

Study burden and risks

Both strategy's of neuromuscular block are part of the routine clinical care in anesthesia. No additional risk are therefore expect within the study population. Patients are only required to fill in questionnaires at 4 different moments.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patients scheduled for elective laparoscopic procedure with a complexity according to the BUPA classification for case complexity: *MAJOR*, *MAJOR PLUS* or *COMPLEX MAJOR*
• ASA class I-III
• >= 18 years of age

• Ability to give oral and written informed consent

Exclusion criteria

• Low or intermediate complexity laparoscopic procedures (BUPA *SIMPLE* or *INTER*)
• Known or suspected neuromuscular disorders impairing neuromuscular function
• Allergies to muscle relaxants, anesthetics or narcotics mentioned
• A (family) history of malignant hyperthermia
• Women who are or may be pregnant or are currently breast feeding
• Chronic use of any type of opioid or psychotropic drug
• Use of NSAID*s shorter than 5 days before surgery for the treatment of chronic pain
• Indication for rapid sequence induction
• Contra-indication for sugammadex use (e.g. known sugammadex allergy or GFR<30 ml/min)

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):	11-02-2020
Enrollment:	508
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-01-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-07-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-09-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-09-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	17-10-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	25-01-2024
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	NL70081.058.19