A study on the effect of deep neuromuscular block on perioperative parameters

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22375

Source
NTR

Brief title
RetroBLISS

Health condition

Surgery for various indication under general anesthesia

Sponsors and support

Primary sponsor: Leiden University;
Source(s) of monetary or material Support: Merck & Co. Philadelphia

Intervention

Outcome measures

Primary outcome

Drug dose, blood pressure, heart rate, bispectral index, postoperative pain, complication rate, re-admission.

Secondary outcome

None

Study description

Background summary

Deep Neuromuscular Block (NMB) is associated with improved ratings of the quality of the surgical field in a number of surgical procedures including urological and gynecological surgeries.1 Recent data from the BLISS 3 trial additionally suggests that a deep NMB is associated with improved postoperative outcomes in terms of reduced pain in the PACU and on the ward.2 Consequently, the number of patients that receives a deep NMB has dramatically increased in our hospital. For example, currently all retroperitoneal surgeries in urology (nephrectomies, prostatectomies, lymph node removal), open eye surgeries and intracerebral vascular surgeries (eg., intracranial thrombectomies) are performed under deep NMB according to strict guidelines (ie. TOF zero, PTC 1-5).

Evidence demonstrating the benefit of a deep NMB or the absence of such benefit on outcomes apart from the subjective impressions of the surgeon is lacking. Additionally, there are no real-world data available of the deep NMB as all of the above mentioned benefits are obtained from well-controlled clinical trials. Hence, the current project aims to collect the characteristics of the deep NMB and expand the data collection to the post-anesthesia care unit and the ward. One example of a data gap is that we remain uniformed whether patients following a deep NMB experience less pain. This study aims to address the data gap on deep NMB by retrieval of objective data from LUMC database in patients undergoing elective surgery under deep NMB.

The main objective of the current retrospective analysis is to examine perioperative parameters in deep NMB. Historical control data of non-deep NMB cases will be examined for comparison.

Study objective

Deep neuromuscular block has advantages over a moderate neuromuscular block in term of outcome (pain, respiration) but has otherwise no effects on the patient

Study design

Retrospective data retrieval, no time points specified.

Intervention

Observational retrospective data retrieval from the patient data monitoring system.

Contacts

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Eligibility criteria

Inclusion criteria

-Patients that received a deep neuromuscular block in the period July 2015-december 2016

-urological, surgical, ophthalmologic and neurosurgical procedures.

-age 18 years or older

-Patients matched for sex and procedure that received general anesthesia under moderate block (historical cohort)

Exclusion criteria

-Age < 18 years.

-Procedures other than urology, surgery, ophthalmology or neurosurgery.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-01-2017
Enrollment:	230
Type:	Unknown

Ethics review

Positive opinion

Date:	27-12-2016
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	NL6034
NTR-old	NTR6165
Other	METC LUMC : G16.041

Study results