Recovery of carotid body function after full recovery neuromuscular block

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To study the time needed for full recovery of carotid body response to hypoxia (ie. hypoxic ventilatory response, HVR) after full recovery of neuromuscular block with and without reversal with sugammadex

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

Summary

ID

NL-OMON52207

Source
ToetsingOnline

Brief title
Breath 2 trial

Condition

- Other condition

Synonym
perioperative muscle relaxation

Health condition

perioperatieve verslapping

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Merck

Intervention

Keyword: Neuromuscular block, respiration, reversal

Outcome measures

Primary outcome

The primary end-point is the time difference to full recovery of the hypoxic

ventilatory response after recovery of NMB

Secondary outcome

The dynamics of carotid body function at different levels of NMB and during

recovery.

The influence of sugammadex reversal on CB function recovery

Study description

Background summary

The ventilatory response to hypoxia is a life-saving chemoreflex that originates from the carotid bodies. Dysfunction of this reflex renders patients at risk for respiratory adverse events such as hypoxia. Numerous drugs depress this reflex, including muscle relaxants which are routinely used during general anesthesia. Muscle relaxants directly block acetylcholine mediate signal transmission at the carotid bodies and they do so even at very low concentrations. In addition, data from the BREATH trial showed that, even after full recovery of neuromuscular block, the ventilatory response to hypoxia has not recovered fully in a significant subset of subjects.

Study objective

To study the time needed for full recovery of carotid body response to hypoxia (ie. hypoxic ventilatory response, HVR) after full recovery of neuromuscular

block with and without reversal with sugammadex

Study design

randomized, cross over, experimental trial

Study burden and risks

The administration of a low dose of rocuronium leads to some degree of muscle relaxation (TOF ratio remains 0.7 or higher).
Similar muscle relaxation also occurs in postoperative patients. This degree of muscle relaxation generally induces, diplopia and dysarthria.
Given the presence of a doctor, the continuous monitoring of vital signs and the possibility of immediate reversal of the neuromuscular block, the direct risks are minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

Age: >18 years old

Exclusion criteria

BMI index; >30 kg/m2
Known or suspected neuromuscular disorders impairing neuromuscular function;
Allergies to muscle relaxants, anesthetics or narcotics;
A (family) history of malignant hyperthermia or any other muscle disease;
Any neurological or psychiatric illness (including a history of anxiety).
ASA class 3 or higher

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-01-2022
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	Leiden Gas Mixer

Registration:	No
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:	11-02-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-10-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	01-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	09-12-2022
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
EudraCT	EUCTR2020-000057-27-NL
CCMO	NL78678.058.21