The BREATH study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27296

Source
Nationaal Trial Register

Brief title
BREATH

Health condition

Carotid bodies; partial neuromuscular block; hypoxic and hypercapnic ventilatory respons; dynamic end-tidal forcing technique; rocuronium; sugammadex; neostigmine;

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

- The effect of partial neuromuscular blockade (NMB; TOF ratio 0.8 and 0.6) induced by low-dose rocuronium on the ventilatory response to isocapnic hypoxia and the effect over time (from TOF 0.6 to TOF 1.0) of the reversal by sugammadex, neostigmine or placebo in healthy volunteers

Secondary outcome

To assess the effect of partial NMB (TOF ratio 0.6) induced by low-dose rocuronium on the ventilatory response to hypercapnia and effect over time (from TOF 0.6 to TOF 1.0) of the reversal by sugammadex, neostigmine or placebo in healthy volunteers.

Study description

Background summary

This is a randomized, double blind, 3-arm, placebo controlled parallel study on the influence of reversal of a partial NMB on carotid body function following rocuronium administration. Healthy volunteers will be randomized to receive either placebo (Group1, n = 12), neostigmine (1 mg. n =12) or sugammadex (2 mg/kg, n = 12) following a continuous rocuronium infusion for 120 min aimed at a TOF ratio of 0.8 for 1 h followed by 0.6 for another hour. Prior to the rocuronium infusion and during the infusion, ventilatory responses to isocapnic 2-min hypoxic pulses will be obtained as well as the (hyperoxic) ventilatory response to hypercapnia. After the 120 min infusion and the administration of reversal agents, the ventilatory response to hypoxic pulses will be obtained at 5 min interval for at least 60 min. In case the response has not returned to pretreatment control values, additional responses will be obtained. Hereafter, a final ventilatory response to carbon dioxide will be obtained (at hyperoxic conditions).

The study was amended as follows (30-jul-2018):
- After baseline respiratory measurements were obtained (acute hypoxic response, AHR, and the hypercapnia ventilatory response, HCVR), rocuronium was administered and titrated to a TOF ratio of 0.7, rather than to 0.6 and 0.8. After the target of 0.7 was reached the respiratory measurements were repeated.
- Thereafter the reversal agents (sugammadex, neostigmine, or placebo) were administered according to randomization.
- Since reversal was relatively fast, we performed two hypoxic steps AHR and one HCVR one specified time point.

Study objective

A. Rocuronium will induce impairment of carotid body function through blockade of cholinergic neurotransmission in carotid bodies resulting in a reduced or absent ventilatory response to isocapnic hypoxia.

B. Sugammadex will completely restore carotid body function following rocuronium administration with full reversal of the ventilatory response to isocpanic hypoxia within 2 min.

C. Neostigmine will cause a protracted reversal of the carotid body function following rocuronium administration with full reversal within 40-60 min.

Study design

Baseline ventilation, ventilatory measurements every 5 min.

Intervention

- Partial neuromuscular block with rocuronium

- Hypoxic and hypercapnic ventilatoy respons

- Antagonizing neuromuscular block with either neostigmine or sugammadex or placebo

Contacts

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Eligibility criteria

Inclusion criteria

Healthy male volunteers aged 18 and older with a body mass index < 30 kg/m2.

Exclusion criteria

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 medical, neurological or psychiatric illness (including a history of anxiety).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-06-2017
Enrollment:	36
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-05-2017
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	NL6253
NTR-old	NTR6427
Other	NL55794.058.15 : P16.025

Study results