The BREATH study

Gepubliceerd: 04-05-2017 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27296

Bron
Nationaal Trial Register

Verkorte titel
BREATH

Aandoening

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

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: LUMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Baseline ventilation, ventilatory measurements every 5 min.

Onderzoeksproduct en/of interventie

- Partial neuromuscular block with rocuronium

- Hypoxic and hypercapnic ventilatoy respons

- Antagonizing neuromuscular block with either neostigmine or sugammadex or placebo

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-06-2017
Aantal proefpersonen:	36
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-05-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6253
NTR-old	NTR6427
Ander register	NL55794.058.15 : P16.025

Resultaten