

Effect of neuromuscular blockade reversal with sugammadex on oxygenation, pain and arousal states in the post-anesthesia care unit

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We hypothesize that reversal with sugammadex leads to favorable postoperative respiratory conditions, less sedation and lower pain levels as compared to reversal with the (traditionally used) acetylcholinesterase inhibitor neostigmin

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

Samenvatting

ID

NL-OMON26051

Bron

Nationaal Trial Register

Verkorte titel

Neuropa

Aandoening

Sugammadex, Train of four ratio, Respiration, Post operative

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)

Overige ondersteuning: MSD

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Postoperative SpO2 level obtained at 2-min interval for 45 minutes and the need for supplemental oxygen

Toelichting onderzoek

Achtergrond van het onderzoek

Muscle relaxants are routinely used during general anesthesia. However, when at the end of surgery reversal is suboptimal, its use is associated with an increase in postoperative complication, most importantly hypoxemia in the first 30-45 minutes in the recovery room. Since 2008 an intense and rapid reversal of a rocuronium-induced neuromuscular block is possible with the use of sugammadex.

The current study is aimed at assessing the effect of sugammadex on the postoperative respiratory condition compared to the (traditionally used) neostigmin. The patient will be randomized to receive sugammadex or neostigmin as reversal of the neuromuscular block and respiratory conditions will be monitored during the first 45 minutes at the recovery room.

Doel van het onderzoek

We hypothesize that reversal with sugammadex leads to favorable postoperative respiratory conditions, less sedation and lower pain levels as compared to reversal with the (traditionally used) acetylcholinesterase inhibitor neostigmin

Onderzoeksopzet

- Peroperative: bispectral index, TOF count, TOF ratio
- Postoperative: SpO2, respiratory rate, oxygen consumption, pain, sedation, occurrence of nausea/vomiting, blood pressure, heart rate

Onderzoeksproduct en/of interventie

According to the randomization list the patient will receive at the end of the surgery sugammadex 2mg/kg or neostigmine 2.5 mg + atropine 1 mg at a NMB level of TOF>0

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age >18 years
- Body mass index < 35 kg/m²
- ASA class I-III
- Patients scheduled for elective surgery requiring anesthesia with the use of neuromuscular blocking agents.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Known or suspected neuromuscular disorder impairing neuromuscular function
- Allergie to muscle relaxants, anesthetics or narcotics.

- A (family) history of malignant hyperthermia
- Women who are or may be pregnant or are currently breast feeding
- Contraindication for the use of neostigmine (intestinal obstruction, COPD GOLD 4 or abnormal heart rhythm)
- Surgery requiring neuraxial anesthesia/analgesia
- Preoperative cognitive dysfunction or mental disabilities
- Preexistent significant pulmonary disease with preoperative SpO₂<90%
- Preoperative ICU treatment/intubation (ICU patient);
- Need for postoperative ICU treatment or ventilation
- Renal insufficiency (GFR<30 mL/min or oliguria < 0.5 mg/kg/h)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-10-2014
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 11-08-2015

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	NL5262
NTR-old	NTR5378
Ander register	Medisch Ethische Toetsingscommissie (METC) : P14.060

Resultaten