

# **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

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	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 SpO<sub>2</sub> 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: SpO<sub>2</sub>, 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

LUMC, Anesthesiology, P5, Albinusdreef 2

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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/m<sup>2</sup>
- 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
- Allergy 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 SpO<sub>2</sub><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
Blinding:	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