Street Fitness In surgical patieNts undergoing general anesthesia after reversal of neuromuscular rest blockade with sugammadeX (SFINX study).

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The main aim of the present study is i)To assess whether sugammadex has a positive effect on the post-operative alertness of the patients, and ii) to assess the nature, magnitude and the time of onset of this effect (if any).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Interventional

Summary

ID

NL-OMON36651

Source
ToetsingOnline

Brief title
The effect of sugammadex on post-operative alertness and revovery.

Condition

- Therapeutic procedures and supportive care NEC

Synonym
post-operative alertness and recovery, street fitness

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Industry (MSD;see section J;additional remarks) ,Select

Intervention

Keyword: neuromuscular blockade, post operative alertness, recovery, sugammadex

Outcome measures

Primary outcome

At baseline (1 day before surgery), and 30, 60, and 120 minutes after the TOF ratio of ~0,9 has been reached, the following commonly used, and non-invasive cognitive evaluations/scoring lists will be carried out in a subsequent order to assess recovery and psychomotor function:

Modified Aldrete score

The modified Aldrete score (see Appendix 2) assesses the degree of post-anesthesia recovery, based on ability to move extremities, respiration and circulation status, consciousness and oxygen saturation. Each item is scored from 0 (poor) to 2 (good). >=9 points are needed for recovery to be confirmed, i.e. the patient is ready for discharge from the PACU.

Trail making test

This test is used to measure visual conceptual and visual motor tracking 29. Normally, the entire test can be completed in 5 to 10 minutes. Only part A of this test will be performed. Since it is a test of speed, the examiner must stress the importance of time and efficiency. Part A consists of encircled numbers from 1 to 25 randomly spread across a sheet of paper. The object of the

test is for the subject to connect the numbers in order, beginning with 1 and ending with 25, in as little time as possible. The number of failures to connect and the distance from the actual line to the number will be determined.

Maddox wing test

With the Maddox Wing instrument an imbalance in the extra-ocular muscles of the eyes (degree of strabismus) will be measured, where the field of vision is divided by oblique and vertical wings such that the arrow is seen by the right eye and a numbered scale in prism diopters by the left.

Visual Analogue Scales for patient and observer to rate post-operative alertness and recovery.

Secondary outcome

Additional relevant data to be collected include gender, age, relevant medical history, type of surgery, anticipated duration of surgery, total dose of propofol and remifentanil, total dose of rocuronium, time of rocuronium administration(s) relative to start of anesthesia (T=0), other drugs administered for medical reasons that could influence the outcome of the study evaluations, end of surgery relative to T=0, time TOF~ 0,9 has been reached relative to T=0, time start and end of evaluations relative to T=0, any perioperative complication, and adverse events.

Study description

Background summary

The number of ambulatory surgical procedures is increasing rapidly. Surgery without one or more overnight stays in the hospital is appreciated by most patients and has considerable economic and efficiency advantages. Recovery from outpatient anesthesia includes dissipation of anesthetics agents, normalization of physiological function, observation for medical or surgical complications, treatment of immediate side effects of anesthesia and surgery and, ultimately, discharge and return home. Street fitness implies that the patient is not only ready to go home, but is also capable of safely taking part in the traffic. A full recovery of cognitive functions is part of this stage. Neuromuscular blocking agents (NMBAs) are commonly used during surgery to facilitate endotracheal intubation, allow assisted or controlled ventilation, and let surgery proceed easily. Sugammadex (Bridion®) is approved in Europe for routine clinical use to reverse neuromuscular blockade induced by steroidal non-depolarizing muscle relaxants and has been registered in the Netherlands since 2008. Several anesthesiologists from all over the world, have independently reported that patients seem to be more alert in the early phase of recovery after reversal of NMB with sugammadex compared to reversal with a cholinesterase inhibitor or spontaneous recovery. However, these observations have not been substantiated in a clinical study.

Study objective

The main aim of the present study is i)To assess whether sugammadex has a positive effect on the post-operative alertness of the patients, and ii) to assess the nature, magnitude and the time of onset of this effect (if any).

Study design

This is a randomized, controlled observer-blind single centre phase IV study. Upon After stratification for type of surgery and age patients will be randomized to receive sugammadex (arm A), neostigmine/atropine (Arm B) or no reversal agent (arm C).

Intervention

Anesthesia will be standardized according to the usual protocol. At the end of the surgery when TOF ratio is ~0,9, and approximately 70-80% of nicotine receptors are still blocked by rocuronium, patients will receive either sugammadex (2 mg/kg iv), neostigmine,04 mg/kg iv plus atropine 0.015 mg/kg iv, or no reversal agent.

Study burden and risks

Anesthesia and surgical procedures will be according to the usual clinical

procedures. At the end of the surgery, patients will either receive sugammadex, or neostigmine plus atropine to reverse neuromuscular blockade (both drugs are registered, safe and commonly used in daily clinical practice), or no reversal agent.
At basline (1 day before surgery, and at 30, 60 and 120 minutes after the end of the operation), a serie of non-invasive (cognitive) assessments will be assessed to evalluate post operatve alertness and recovery. Expected duration is 15-20 minutes per measuring moment (in total 4 measuring moments). Outcomes of this present study will provide insight if the administration of sugammadex will positively affect post operative alertness and recovery which may have important cllinical and economical implications.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Males and females.
- Age 18-65 years.
- Able to perform the study assessments.
- ASA classification 1 or 2
- Medical need for general anesthesia and neuromuscular blockade.
- NMB with the standard dose of rocuronium. If the surgery lasts longer than 75 minutes the patient will be excluded.
- Minor surgical and gynecological procedures that require tracheal intubation and mechanical ventilation.
- Signed informed consent.

Exclusion criteria

- Contra-indications for rocuronium, sugammadex, neostigmine and/or atropine.
- Concomitant conditions or diseases that might interfere with the study assessments.
- Concomitant treatment with any experimental drug within 4 weeks before surgery.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2011
Enrollment:	90
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bridion
Generic name:	Sugammadex
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	25-01-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-09-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2011-000157-23-NL
CCMO	NL35385.091.11