# Effect of deep neuromuscular block and variations in arterial PCO2 on the surgical rating scale, extubation conditions and postoperative conditions following reversal with sugammadex

Published: 30-09-2013 Last updated: 22-04-2024

To assess whether the implementation of a deep neuromuscular block (NMB) (PTC 1-2) combined with induction of relative hypocapnia creates optimal surgical conditions as measured by the surgeon (using the 5-point Leiden surgical rating scale) versus...

| Ethical review        | Approved WMO   |
|-----------------------|--|
| Status                | Recruitment stopped  |
| Health condition type | Miscellaneous and site unspecified neoplasms malignant and unspecified |
| Study type            | Interventional   |

# Summary

### ID

NL-OMON38910

**Source** ToetsingOnline

Brief title BLISS 2

# Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Renal and urinary tract therapeutic procedures

### Synonym

niercelcarcinoom, prostaatcarcinoom

### **Research involving**

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Human

### **Sponsors and support**

**Primary sponsor:** Leids Universitair Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W,Merck

### Intervention

Keyword: neuromuscular block, surgical conditions

### **Outcome measures**

#### **Primary outcome**

To study the surgical conditions in patients undergoing laparoscopic renal or prostate surgery during low and normal arterial PCO2 levels as assessed by the surgical rating scale.

#### Secondary outcome

To assess the relation between scoring of surgical conditions by the surgeon and video assisted scoring of surgical conditions.

To study the hemodynamic conditions during low arterial CO2 concentration (3.5

kPa or 26.3 mmHg) versus normal arterial CO2 concentration (6.5-7.0 kPa or

48.8-52.5 mmHg)

To assess respiratory function, pain, nausea/vomiting postoperative following anesthesia maintained at low or normal arterial CO2 concentration To assess whether a deep neuromuscular block (PTC 1-2) combined with induction of relative hypocapnia (PaCO2 3.5 kPa or 26.3 mmHg) and reversal with sugammadex (4 mg/kg) will result in extubation within 5-min following reversal and excellent postoperative respiratory conditions.

# **Study description**

#### **Background summary**

surgical conditions during laparoscopy are largely determined by the level of neuromuscular block. Deep neuromuscular block at 1-2 twitches post titanic count has shown to provide superior surgical conditions compared to a moderate neuromuscular block of 1-2 twitches train of four. However, despite a deep neuromuscular block measured peripherally at the nervus ulnaris, surgical conditions may still be suboptimal. A major factor influencing the surgical conditions includes involuntary movements by the diaphragm. These involuntary movements are triggered in the brainstem by local carbon dioxide levels. In this study we intend to study the effect of variations in the arterial CO2 concentration on the surgical conditions as assessed by the surgical rating scale

#### **Study objective**

To assess whether the implementation of a deep neuromuscular block (NMB) (PTC 1-2) combined with induction of relative hypocapnia creates optimal surgical conditions as measured by the surgeon (using the 5-point Leiden surgical rating scale) versus a deep neuromuscular block (PTC 1-2) combined with normocapnia.

### Study design

This is a single-center randomized comparative single-blinded interventional study

#### Intervention

Two patient groups, one in which the arterial CO2 concentration is controlled to values of 3.5 kPa or 26.3 mmHg (GROUP 1; n=20), the other in which the target is 6.5-7.0 kPa or 48.8-52.5 mmHg (GROUP 2; n=20). Variations in arterial CO2 concentration are applied by changes in minute ventilation. All surgical procedures will be performed by one surgeon.

#### Study burden and risks

After induction of anesthesia, an arterial line will be placed in one of both radial arteries for hemodynamic monitoring and drawing of bloodsamples ( $12 \times 2$  ml = 24ml). This is a standard anesthesiological procedure and is used for various (other) procedures.

# 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**

(i) Patients diagnosed with renal or prostatic disease who are will undergo an elective laparoscopic renal surgical procedure or laparoscopic prostatectomy;
(ii) ASA class I-III
(iii) > 18 years of age;
(iv) Ability to give oral and written informed consent.

### **Exclusion criteria**

- (i) Known or suspected neuromuscular disorders impairing neuromuscular function;
- (ii) Allergies to muscle relaxants, anesthetics or narcotics;
- (iii) A (family) history of malignant hyperthermia;
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(iv) Women who are or may be pregnant or are currently breast feeding;

(v) Renal insufficiency, as defined by serum creatinine x 2 of normal, or urine output < 0.5 ml/kg/h for at least 6 h. When available, other indices will be taken into account as well such as glomerular filtration rate < 60 ml/h and proteinuria (a ratio of 30 mg albumin to 1 g of creatinine).

(vi) Previous retroperitoneal surgery at the site of the current surgery.

(vii) Body mass index > 35 kg/m2

(viii) Chronic obstructive pulmonary disease GOLD 2-4 or a FEV1 less than 70% predicted or VC less than 70% predicted

(ix) chronic pulmonary disease with altered lung physiology (eg. sarcoidosis, cycstic fibrosis, obstructing pulmonary tumors, previous lung surgery)

# Study design

### Design

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

### Recruitment

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| NL                        |                     |
|---------------------------|---------------------|
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 27-01-2014          |
| Enrollment:               | 40                  |
| Туре:                     | Actual              |

# **Ethics review**

| Approved WMO       |  |
|--------------------|--|
| Date:              | 30-09-2013                                       |
| Application type:  | First submission                                 |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

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# **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** CCMO **ID** NL45461.058.13