A comparison between different methods to measure respiration rate.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25006

Source
NTR

Brief title
The Respir8 Study

Health condition

- respiration rate
- SpO2
- Respir8

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Leiden University Medical Center

Intervention

Outcome measures

Primary outcome

1. Respiratory rate measured by the Respir8, the stopwatch method, capnography and ECG;

2. Oxygen saturation.

Secondary outcome

No secondary outcomes will be measured in this study.

Study description

Background summary

The trial consist of three phases. Phase 1 and 2 are in healthy volunteers. Phase 3 is in patients.

Phase 1: Observe respiratory rate under normal breathing conditions and with a 50% increase and decrease in respiratory rate. RR will be measured with the new device the Respir8. Data collected from this device will be compared with the conventional methods capnography and stopwatch method.

Phase 2: Observe respiratory rate and SpO2 after an iv single bolus of remifentanil (50 ug/70 kg) under normal are conditions and with 50% oxygen. This allows assessment of the difference in speed of response between RR and SpO2 measurements.

Postoperative patients:

Phase 3: observe respiratory rate with the Respir8, capnography, stopwatch method and ECG-method and oxygen saturation in the recovery room in postoperative patients. This will allow comparison between the different methods regarding the best way to monitor the airway after surgery.

Study objective

We hypothesize that the Respir8 is more accurate and reliable in measuring respiration rate than conventional methods like the stopwatch method (counting respiration rate by hand), capnography and the ECG-method.

Furthermore we hypothise that insufficient breathing (and by this lowering of the oxygen

saturation) will be noticed earlier by the respir8 compared to the conventional oxygen saturation measurement method (SpO2-probe).

Study design

Phase 1. Respiratory rate will be measured for 1 minute every 5 minutes over a period of 20 minutes;

Phase 2. Respiratory rate and Spo2 will be monitored continuously for 20 minutes;

Phase 3. Respiratory rate and SpO2 will be measured will be collected every 10 minutes for the period the patient is in the recovery room.

Intervention

Healthy volunteers:

Phase 1: Observe respiratory rate under normal breathing conditions and with a 50% increase and decrease in respiratory rate;

Phase 2: Observe respiratory rate and SpO2 after an iv single bolus of remifentanil (50 ug/70 kg) under normal are conditions and with 50% oxygen.

Postoperative patients:

Phase 3: Observe respiratory rate (with three methods) and oxygen saturation on the recovery room in postoperative patients.

Contacts

Public
Leiden University Medical Center (LUMC),
Department of Anesthesiology,
P.O. Box 9600
Albert Dahan
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301
Scientific
Leiden University Medical Center (LUMC),
Department of Anesthesiology,

P.O. Box 9600
Albert Dahan
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301

Eligibility criteria

Inclusion criteria

Healthy volunteers and post-operative patients being able to give informed consent.

Exclusion criteria

For healthy volunteers:

1. Obesity (BMI > 35);

2. Presence of medical disease (heart-, lung-, liver-, kidney-, neurologic disease; diabetes m.; pyrosis; diaphragmatic hernia);

3. Presence of psychiatric disease;

4. History of chronic alcohol or illicit drug use;

5. Allergy to study medications;

6. Expected difficulty to hold to subject on mask causing leakage and inability to perform mask ventilation (i.e., Mallampati classification 3 or greater);

7. For females, we require the use of contraceptives.

For post-opartive patients: Presence of cardiopulmonary diseases.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2011
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-11-2011
Application type:	First submission

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
NTR-new	NL3015

Register	ID
NTR-old	NTR3163
Other	METC LUMC : P11-172
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A