A comparison between different methods to measure respiration rate.

Gepubliceerd: 26-11-2011 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25006

Bron
NTR

Verkorte titel
The Respir8 Study

Aandoening

- respiration rate
- SpO2
- Respir8

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Leiden University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2011
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-11-2011
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	NL3015
NTR-old	NTR3163
Ander register	METC LUMC : P11-172
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A