NAVA study.

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NAVA (neurally adjusted ventilatory assist) is a newform of artificial respiration, based on the electrical activity of the diafragma. We want to investigate wether there are fysiological differences between the conventional mode and NAVA.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23872

Bron
NTR

Aandoening

NAVA
Comfort
Synchrony - Synchroon
Work of breathing - Ademarbeid
Pediatrics- kinderen
Neonaten
Premature - prematuren

Ondersteuning

Primaire sponsor: Performer: PICU and NICU Sophia children's Hospital, Erasmus MC, the Netherlands
Overige ondersteuning: fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Fysiological measurements: Heartrate, saturation, bloodpressure;
2. Respiratory measurements: Peakpressure, mean pressure, oxygen demand, resp frequenty, NAVA-level, Edimax, Edi min.

Toelichting onderzoek

Achtergrond van het onderzoek

In this study we want to see if NAVA is applicable in the neonatal and pediatric patient. We want to investigate what fysiological differences there might be between NAVA and a conventional mode.

Doel van het onderzoek

NAVA (neurally adjusted ventilatory assist) is a newform of artificial respiration, based on the electrical activity of the diafragma. We want to investigate wether there are fysiological differences between the conventional mode and NAVA.

Onderzoeksopzet

1. Fysiological and respiratory parameters every minute;

2. Comfortscore every half our;

3. Position of catheter, when a chest X-ray is taken.

Onderzoeksproduct en/of interventie

NAVA working mechanism:

NAVA stands for neurally adjusted ventilatory assist. This mode of mechanical ventilation is based on the neural respiratory output from the patient itself.
This new mode is only available on the Servo I, produced by Maquet Solna Sweden.

The act of breathing depends on rhytmic discharge from the respiratory center of the brain. This discharge travels along the phrenis nerve and excites the diaphragm muscle cells. The diaphragm contracts and as a result there is a pressure drop in the lungs causing air to flow into the lungs.

Respiratory support is given on the basis of measurement of the electrical excitation of the diafragm (Edi signal). A naso-gastric

tube, wich has multiple electrode rings placed on the distal part of the tube, is put in the proper position (the electrodes will be placed at diafragm level.). The electrical signal of the diafragm then can be detected and a software program filters the signal from artefacts (eg the electrical excitation of the heart). The Edi signal is displayed on the monitor of the Servo I.

Because both the patient and the machine act upon the same signal there is an instantaneous support from the machine.

NAVA is synchronous with the patient's own respiratory frequency and the support level is propotional too the magnitude of the Edi signal. This means that if the signal is stronger the support will be higher and vice-versa. This new mode of ventilatory support may give the patient improved synchrony, lung protection and patient-comfort.

First we insert an Edi catheter, which measures the electricalsignal at diafrgam level. Then we will observe the fysiological, respiratory parameters and take a comfortscore.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Pediatric ward:

1. Fi02% < 40%;

2. PC < 15 cm H20 above PEEP, PRVC Tv 6-8 ml/kg (peak pressure < 20 cm H20;

3. PEEP <8 cm H20;

4. Spontaneus triggering.

Neonatology:

1. Fi02% < 30%, PC < 15 cm H20 above PEEP;

2. PEEP < 6 cm H20;

3. Gestational age> 29 weeks or weight > 1250 grams.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Pediatric ward:

1. ECMO treatment;

2. No informed consent from parents;

3. Neurological illness or trauma;

4. CHD;

5. Oesophagus atresia;

6. Extubation within 24 hours.

Neonatology ward:

1. No informed consent from parents;

2. Hemodynamic instability;

3. IVH, asphyxia, convulsions;

4. Sedation, therofore no spontaneus breathing;

5. Possible extubation within 24 hours.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	18-10-2009
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	15-10-2009
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	NL1949
NTR-old	NTR2067
Ander register	MEC : 2009-213
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A