NAVA on the PICU and NICU: Feasibility study with children needing mechanical ventilation

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Feasibility study of the option NAVA (Neurally adjusted ventilatory assist) on the Servo-i in ventilated children in the age of 0-18 on the PICU and the NICU of the Erasmus MC -Sophia Childrens hospital in Rotterdam.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON33510

Source
ToetsingOnline

Brief title
feasibility study of NAVA in children and neonates

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
respiratory problems and respiratory failure

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,MAQUET, bruikleen van de software modules

Intervention

Keyword: Mechanical ventilation, NAVA, NICU, PICU

Outcome measures

Primary outcome

Primair study parameters

Practical feasibility:

• Is it easy to bring in the Edi catheter and is it easy to measure the length

you need for a specific child?

• Can you fix the Edi catheter well because of the risk of aspiration?

• Is it possible to bring in an Edi catheter if there is already a enteral

feeding tube (to the stomach) in situ? And does the other enteral feeding tube

(located in duodenum) influence the EAdi signals?

• Do we get a good EAdi signal on the Servo-i?

Secondary outcome

Secondary study parameters

• Do the peak pressures stay below 35 cm H2O and do the difference between peak

and PEEP stays between 15 en 20 cm H2O above PEEP? This because of preventing

ventilator induced lung injury

• Is the EAdi signal decreasing when there is a high pressure support?

• What is the effect on the Edi signal after we change from conventional

ventilation to NAVA?

• What is the procedure for decreasing the NAVA level?

Comfort and sedation during NAVA ventilation:

• How comfortable is the patient during NAVA ventilation?

Study description

Background summary

Modes of partial ventilatory assistance are preferred to reduce side-effects and complications associated with controlled mechanical ventilation. With these modes, ventilator cycling is ideally under control of the patient*s own respiratory drive and rhythm, which also influences the ventilatory output to an extent that varies with the different modes. Coordination between spontaneous breathing and mechanical assistance, however , is not guaranteed and a poor interaction between patient and machine may represent a major problem in the ventilatory management of patients with acute respiratory failure. Neurally adjusted ventilatory assist (NAVA), introduced by MAQUET in 2007, is a new form of partial support wherein the machine applies positive pressure throughout inspiration in proportion to the electrical activity of the diaphragm (EAdi) as assessed by trans-esophageal electromyography. The amount of assistance for a given EAdi depends on a usercontrolled gain factor. With intact phrenic nerves, EAdi is the earliest and best signal available to estimate the neural respiratory drive. Because ventilator functioning and cycling are under control of the patient*s respiratory drive and rhythm, NAVA has the potential to enhance patient-ventilator interaction ensuring synchrony and minimizing the risk of over-assistance. The first experimental studies with NAVA seems to confirm this.
Which patient categories gains the best benefit with NAVA needs to be studied. One of the main benefits should be improved patient-ventilator synchronization. Altogether, we can expect patients experience greater respiratory comfort*even those at risk of dynamic hyperinflation. There is less experience with NAVA in children, so there is a need for research : Does NAVA have clinical benefits for ventilated children in comparison to conventional ventilation? In this study we first want to know if NAVA is feasible to use in children with uncomplicated mechanical ventilation.

Study objective

Feasibility study of the option NAVA (Neurally adjusted ventilatory assist) on the Servo-i in ventilated children in the age of 0-18 on the PICU and the NICU of the Erasmus MC -Sophia Childrens hospital in Rotterdam.

Study design

Design

Prospectif observational pilot study with intervention

Intervention

NAVA
First we measure for 3 hours without NAVA with the Edicatheter. After 3 hours we measure with NAVA. The intervention is to activate NAVA and to observe what is happening.

Study burden and risks

There are no direct advantages for the child. Later when we have measured enough parameters we know if NAVA can be used for quicker weaning and more comfort. The results of the research is important for the future. Other children will experience the profit of NAVA. A possible disadvantage for the child can be that a enteral feeding tube that already is in situ will be changed by a Edi catheter which can measure the electrical signals. However the feeding tube would be changed on a regular base, according to the protocol of feeding tubes.
After the child receives the NAVA feeding tube the electrical signal will be measured. To make a comparison between the two methods we want to measure 3 hours with the conventional ventilation. Afterwards we will measure 3 hours with NAVA ventilation. In this second period the machine will react on the electrical signal of the diaphragm. During this period there will be a researcher near the child for the whole time of measuring. If the child will stay for a longer period on the ventilator we will ask the parents for another 6 hours of measuring. Two times 6 hours is the maximum. The Edi catheter will be in situ until the child no longer needs a feeding tube or until the feeding tube needs to be replaced according the policy of the ward.
There will be no risks if the stop criteria will be used properly, an hour after starting NAVA. If the patient worsens in relation to the conventional ventilation we use the next stop criteria:
- Inspiration pressure > 25 cm H20 for NICU and > 35 cm H2O for PICU
- Breathing frequency > 80-100 / min
- Raising of the EtC02 > 2Kpa in comparison to the Et CO2 during conventional ventilation
- Discomfort in children (PICU): COMFORT score >=23 or COMFORT score 11-22 and VISS = 1 (insufficient sedation)
- Discomfort in neonates (NICU): COMFORT Neo score >= 14.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
3015 GJ Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
3015 GJ Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

PICU:
uncomplicated mechanical ventilation:
FiO2 < 40%, PC < or equal to 15 cmH2O above PEEP, PEEP < or equal to 8 cmH2O and spontaneous breathing efforts;
- FiO2< 40%, PRVC with a pressure < 20 cmH2O and a tidal volume of 6-8 ml a kilo and spontaneous breathing efforts.
NICU:
10 neonates with uncomplicated mechanical ventilation.
- FiO2 < 30%, PC < 15 cmH2O above PEEP, PEEP < 6 cmH2O and spontaneous breathing efforts;
- Hemodynamical stable without inotropica
- Weight > 1250 grams or gestational age > 29 weeks

Exclusion criteria

Exclusion criteria PICU:

- No consent of the parents;
- ECMO treatment;
- Other ventilator than the Servo-i
- Neurological disturbances: brain trauma, status epileptica, disturbance of the mitochondria with neurological problems
- Congenital defect of the diaphragm
- Esophagal atresia before surgery
- Extubation possible within 24 hour.;Exclusioncriteria NICU:
- No consent of the parents
- Hemodynamically instable
- Other ventilator than the Servo-i
- Intraventricular hemorrhage, asphyxia, seizure
- Sedation too deep, no spontaneous breathing efforts
- Extubation possible within 24 hour

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2009
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	NAVA option on the Servo i
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-09-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL26857.078.09