# NAVA study.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23872

**Source**
NTR

**Health condition**

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

### Sponsors and support

**Primary sponsor:** Performer: PICU and NICU Sophia children's Hospital, Erasmus MC, the Netherlands
**Source(s) of monetary or material Support:** fund=initiator=sponsor

### Intervention

### Outcome measures

**Primary outcome**

1. Fysiological measurements: Heartrate, saturation, bloodpressure;

2. Respiratory measurements: Peakpressure, mean pressure, oxygen demand, resp

frequenty, NAVA-level, Edimax, Edi min.

### Secondary outcome

1. Comfortscore;

2. Position of the catheter.

## Study description

### Background summary

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.

### Study objective

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.

### Study design

1. Fysiological and respiratory parameters every minute;

2. Comfortscore every half our;

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

### Intervention

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.

## Contacts

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## Eligibility criteria

## Inclusion criteria

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.

## Exclusion criteria

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.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Factorial |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-10-2009 |
| Enrollment: | 10 |
| Type: | Actual |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 15-10-2009 |
| 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 | NL1949 |
| NTR-old | NTR2067 |
| Other | MEC : 2009-213 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A