# The full closed loop ventilation mode Intellivent-ASV: user-friendly and effective mechanical ventilation in high risk postoperative patients on the intensive care unit.

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| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON27583

**Bron**
NTR

**Aandoening**

Intellivent-ASV ventilation mode
Fully closed loop ventilation
Conventional ventilation mode
Postoperative ventilation

### Ondersteuning

**Primaire sponsor:** Catharina Hospital Eindhoven
**Overige ondersteuning:** Fund = initiator = sponsor

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

The effectiveness of IntelliVent-ASV compared to conventional mechanical ventilation:<br>
1. Percentage of mechanical ventilation time in an optimal, acceptable or unacceptable zone.<br>
2. The number of successful extubations (without new intubation <48 hours) within 24 hours, 36uur and 48 hours after surgery.<br>
3. Mechanical ventilation time to extubation measured from the time that the patient has a temperature> 35.5 ° C.<br>
User-friendliness of IntelliVent-ASV compared to conventional mechanical ventilation:<br>
1. Based on the measurement of the number of interactions between the caregiver and the ventilator.<br>
2. Survey of usability and acceptance for the caregivers.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Objective of the study:

The aim of this study is to investigate whether postoperative ventilation with IntelliVent ASV in high risk patients, after cardio-thoracic and abdominal surgery, is as effective, more user-friendly and as safe as compared to the conventional modes of ventilation.

Study design:

This is a prospective randomized study with a control group and a treatment group of postoperative high risk patients. Through randomization will be determined whether the participant, after surgery, will be mechanically ventilated with IntelliVent-ASV and Quickwean or with conventional mechanical ventilation.

Study population:

The study population consists high risk patients after cardio-thoracic or abdominal surgery. These patients were assessed before surgery, according to protocol, to be mechanically ventilated after surgery on the high care unit of the intensive care ward, until they can be extubated.

### Onderzoeksopzet

Primairy outcomes:

- Effectiveness.

1: Percentage of mechanical ventilation time in an optimal, acceptable or unacceptable zone., Timepoints: 48 hours of ventilation;

2: Successful extubations: 48 hours after surgery;

3: Mechanical ventilation time: until extubation or death.

- User-friendliness.

1: Interactions with ventilator: 48 hours;

2: Survey: <24 hours after working with ventilator.

Secondary outcomes:

- Safety.

1: Oxygen saturation <85%: 48 hours of ventilation;

2: Ventilation in an unacceptable zone: 48 hours of ventilation.
- Reliability

1: End tidal CO2 en oxygen saturation: 48 hours of ventilation;

2: Unmeasurable oxygen saturation: 48 hours of ventilation.

- Patient friendliness

1: Agitated moments: 48 hours of ventilation;

2: Opiates, benzodiazepines or haloperidol administration: 48 hours of ventilation.

- Postoperative shunting:

1: End tidal CO2, pCO2, pO2 / FiO2 ratio: until 4 hours after extubation;

2: Postoperative pulmonary atelectasis: <48 hours after surgery.

**Onderzoeksproduct en/of interventie**

- The intervention group will be mechanically ventilated with IntelliVent-ASV after surgery.

- The control group will be mechanically ventilated based on the conventional method, consisting out of pressure or volume-controlled mechanical ventilation, followed by pressure support.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age above 18 years of age.

- Informed consent.

- Body mass index of <35 kg/m2.

- Mechanical ventilation after elective surgery.

- Admission of the patient after surgery is on the high care unit of the intensive care ward for postoperative mechanical ventilation.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- The patient with a medical history of a pneumonectomy or lobectomy.

- The patient wit acute respiratory distress syndrome after surgery.

- The patient with a medical history of COPD Gold 3 or 4.

- The patient is participating in an other postoperative study performed on the intensive care.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 30-10-2016 |
| Aantal proefpersonen: | 400 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

## 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 | NL5779 |
| NTR-old | NTR6061 |
| Ander register | NL58975.100.16 : ARB-code |

# Resultaten