

# Automatic Weaning Using Adaptive Support Ventilation (ASV) \* Effect of an Early Weaning Protocol on Time till Extubation of Coronary Artery Bypass Surgery Patients

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To determine whether ASV with a proactive approach results in shorter weaning time as compared to ASV alone.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Therapeutic procedures and supportive care NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON30838

### Source

ToetsingOnline

### Brief title

ASV weaning

### Condition

- Therapeutic procedures and supportive care NEC

### Synonym

ventilation

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Automation, CABG, Ventilation, Weaning

## Outcome measures

### Primary outcome

Duration of mechanical ventilation.

### Secondary outcome

Length of stay in the ICU.

Number of re-intubations

Number of ABG\*analysis.

## Study description

### Background summary

In the ICU, patients after coronary artery bypass grafting (CABG) wean from the ventilator by using adaptive support ventilation (ASV). In the first hours mechanical ventilation is fully mandatory, and the ventilator delivers all support. If the patient wakes up from anesthesia the ventilator automatically switches to supportive ventilation, after which support is gradually but automatically reduced. This form of weaning is the standard strategy in our department. However, we consider time till extubation in these patients still too long. In the study as proposed we compare time till extubation with standard ASV, with ASV during which IC-nurse/physicians reduce ventilatory support more actively, depending on patient's situation. Both forms of weaning are presently used among other ICUs among the Netherlands and beyond. From the literature and from personal experiences we know both methods are safe.

### Study objective

To determine whether ASV with a proactive approach results in shorter weaning

time as compared to ASV alone.

## **Study design**

Randomized controlled trial.

## **Intervention**

Two weaning strategies are compared - in the control group patients are weaned from the ventilator with ASV; in the study group patients are ventilated with ASV too, but IC-nurses/physicians actively lower support according to a pro-active protocol.

## **Study burden and risks**

The burden and risks for the patients are minimal. Apart from the time consumed for informed consent, in fact there is no burden. No extra blood will be drawn. Experience in our own and other centers have shown that weaning with both strategies is feasible and safe

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

1. Planned and uneventful CABG.
2. Following receipt of verbal and written information about the trial, the patient must provide signed and dated informed consent before any trial related activity is carried out

### Exclusion criteria

1. History of any pulmonary disease.
2. History of any previous pulmonary surgery.
3. Valve surgery.
4. Arrival at the ICU with intra\*aortic balloon pump, or inotropes at a more then usual rate (maximum dosages in ml per hour: dopamine [4], norepinephrine [4], dobutamin [4] or epinephrine [any rate]).

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	128

Type:

Anticipated

## Ethics review

Approved WMO

Application type:

First submission

Review commission:

METC Amsterdam UMC

## 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	NL16393.018.07
Other	volgt