Automatic weaning with adaptive support ventilation (ASV): effect on nurse workload and duration of spontaneous ventilation until extubation

Submission date Recruitment status [] Prospectively reg	jistered
20/12/2005 No longer recruiting [] Protocol	
Registration date Overall study status [] Statistical analys	is plan
20/12/2005 Completed [] Results	
Last Edited Condition category [1] Individual partici	pant data
03/11/2008 Respiratory [] Record updated	in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR154

Study information

Scientific Title

Study objectives

We hypothesise that:

- 1. Adaptive support ventilation (ASV) reduces the number of nurse-ventilator interactions in non-fast track cardiac surgery patients
- 2. ASV lengthens the period of spontaneous breathing, while shortening the total respiratory weaning time

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Mechanical ventilation

Interventions

Patients will be either ventilated in a standard fashion (i.e., pressure controlled mechanical ventilation or pressure support mechanical ventilation) or by ASV.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Number of arterial blood gas (ABG) analyses
- 2. Number of audible alarms
- 3. Number of manual changes in the ventilator settings, including:
- 3.1. Switches from PC to PS (only in the control group)
- 3.2. Changes in minute ventilation (only in the ASV group)
- 3.3. Lowering of PS-level (only in the control group)
- 4. Duration of period of spontaneous mechanical ventilation
- 5. Duration of total period of tracheal intubation

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/10/2005

Completion date

01/10/2006

Eligibility

Key inclusion criteria

- 1. Planned uneventful cardiac surgery i.e. coronary artery bypass graft (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

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

128

Key exclusion criteria

- 1. History of pulmonary disease
- 2. History of pulmonary surgery
- 3. Valve surgery
- 4. Arrival at the IC-unit with IABP or inotropes at a more then usual rate (in ml per hour: dopamine (4), norepinephrine (4), dobutamin (4) or epinephrine [any rate])

Date of first enrolment

01/10/2005

Date of final enrolment

Locations

Countries of recruitment

Netherlands

Study participating centre
Department of Intensive Care
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

Sponsor details

Department of Obstetrics and Gynaecology Meibergdreef 9 Amsterdam Netherlands 1105 AZ

Sponsor type

Hospital/treatment centre

Website

http://www.amc.uva.nl/

ROR

https://ror.org/03t4gr691

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration