Comparison of pressure- and volume-guided fluid management in the critically ill: the PAC-PiCCO trial.

Published: 08-12-2006
Last updated: 20-05-2024

The primary hypothesis of our study is that volumetric monitoring will allow for more effective and targeted fluid administration compared to pressure (PAC) monitoring, thereby allowing the attending physician to better optimize fluid infusion...

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON30367

Source
ToetsingOnline

Brief title
the PAC-PiCCO trial

Condition

- Heart failures
- Ancillary infectious topics

Synonym
haemodynamic monitoring in sepsis and cardiovascular surgery

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: fabrikant Pulsion (leverancier PiCCO).

Sponsoring in het kader van educational grant;geen invloed van de sponsor op de uitvoering van het onderzoek. Vraag G2 daarmee niet van toepassing.

Intervention

Keyword: Fluid loading, PiCCO catheter, Pulmonalis Artery Catheter, pulmonary oedema

Outcome measures

Primary outcome

The primary outcome measures will be ventilator-free days (from inclusion to extubation, with inclusion of re-intubation and ventilator days) in the ICU and length of stay in the ICU and the hospital (until day 28).

Secondary outcome

Secondary outcome measurements will be:

1. Hemodynamic measurements, extra-vascular lung water (EVLW), daily fluid balance, during first 72 h after inclusion (and in the subsequent 72 h when monitoring is again clinically indicated)

2. Daily LIS and organ failure (SOFA, see appendix I), which can be deducted from routine clinical and laboratory values obtained on a daily basis in critically ill patients, during the first 72 h after inclusion (and the subsequent 72 H when monitoring is again clinically indicated)

3. Development of ARDS (see appendix I), until day 28

4. Complications associated with the catheter insertion procedure (both immediate, eg arterial puncture, bleeding or pneumothorax, and delayed, pneumothorax within 24 days).

5. ICU mortality and hospital mortality (until day 28)

Study description

Background summary

The risk for developing ARDS after cardiopulmonary bypass surgery, major vascular surgery, or multiple trauma has been reported to range from 10% to 30%; in patients with severe sepsis this number may be even higher (1). Consequently, fluid management is of great importance in these patients; excessive fluid administration may increase the risk of pulmonary oedema, while restricting fluids may lead to intravascular volume depletion with hypotension and, potentially, renal failure and even multiple organ dysfunction. Getting the balance just right is of the utmost importance in these patients.

Study objective

The primary hypothesis of our study is that volumetric monitoring will allow for more effective and targeted fluid administration compared to pressure (PAC) monitoring, thereby allowing the attending physician to better optimize fluid infusion strategies in the first 72 hours after study inclusion. The hypothesis is that use of the volumetric (PiCCO) monitoring strategy will limit fluid overloading and thereby decrease the weaning period and length of stay in the ICU and the hospital. The null hypothesis is that there is no difference between volume (PiCCO) and pressure (PAC) monitoring.

Study design

Patients will be randomized for (fluid) management guided by PAC measurements or PiCCO during for the first 72 hours after inclusion in the study (since the PAC is routinely removed 72 h after insertion to avoid infections). Colloid fluids (gelatin or starches) will be given in bolus doses of 250-500 mL per 30 min when clinically indicated (determined by the attending physician based on clinical parameters and on the PAC or PiCCO data). Clinical reasons for fluid administration will include (as a guideline): tachycardia; hypotension; oliguria (<0.5 mL/kg/h); low flow state (cardiac index <2.1 L/min/m2); low venous hemoglobin saturation (<70 %); peripheral perfusion deficits, either alone or in combination, at the discretion of the attending physician. Vasoactive drugs will be administered and dosed on clinical grounds, as decided by the attending physician, when maximum values for fluid therapy (see below) have been reached. Reasons to administer vasoactive drugs will include persistent and fluid-refractory hypotension, impaired tissue oxygen delivery, lactic acidosis, oliguria and others. After the initial 72 hour period patients will be treated at the discretion of the attending physicians. Nevertheless, the patient will receive a PAC of PiCCO monitoring in the course of disease, for 72 h, as originally randomized, when clinically indicated and pulmonary

oedema can be suspected on the basis of either deterioration, necessitating treatment changes, of gas exchange, radiography, ventilatory settings (when still on mechanical ventilation), or combinations. Similar monitoring and treatment rules as in the first study period will apply.
The hemodynamic monitoring protocol for each arm will include either PAC-derived pressures or PiCCO-derived volumetric variables for the first 72 hours (and the subsequent 72 h period when monitoring is again clinically indicated).

Study burden and risks

NA (possibly lower risk of procedural complications in the PiCCO group compared to the routine procedure (=PA catheter placement), this is one of the questions to be addressed in this study).

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
Nederland
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Invasive mechanical ventilation, regardless of mode and level of support. Presence of a clinical indication for invasive hemodynamic monitoring with filling pressure and cardiac output measurements by PAC. The indication for PA catheterization will be determined and documented by the attending physician. Reasons may include (but are not necessarily limited to): suspected hypovolemic hypotension; shock of unknown origin; prior or concurrent (suspected) cardiac dysfunction; and (impeding) acute renal failure

Exclusion criteria

Age <18 or >80 years
Pregnancy
Pre-terminal illness with life expectancy <24 hours
Inclusion in other trials
Known cardiac or vascular aneurysm
Known pulmonary hypertension (MPAP above 50 mm Hg).
No informed consent (-by proxy).

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2005
Enrollment:	120
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	NL14119.029.06