PERFORMANCE EVALUATION OF ARTERIAL PRESSURE CARDIAC OUTPUT SYSTEMS AS COMPARED TO STANDARD THERMODILUTION AND OTHER ALTERNATIVE CARDIAC OUTPUT MEASUREMENTS
Protocol Number: 2005-03
Revision C
Effective date: February 10, 2006

Published: 21-08-2007
Last updated: 20-05-2024

The purpose of this study is to evaluate accuracy of Cardiac Output measurements by comparing the Cardiac Output calculated by Arterial Pressure based Cardiac Output (APCO) and by other well accepted indicator dilution techniques, as well by…

Ethical review	Approved WMO
Status	Will not start
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON29845

Source
ToetsingOnline

Brief title
MASTERMIND

Condition

- Heart failures
- Cardiac therapeutic procedures

Synonym
Measurement of the performance of the heart

Research involving
Human

Sponsors and support

Primary sponsor: Edwards Lifesciences LLC
Source(s) of monetary or material Support: Edwards Lifesciences LLC

Intervention

Keyword: Cardiac Output, FloTrac, Monitoring, Vigileo

Outcome measures

Primary outcome

Intermittent Cardiac Output (ICO)

Continuous Cardiac Output (CCO)

Secondary outcome

Demographics, Reason for Hemodynamic monitoring, Pre-existing conditions, Heart

rate, Arterial Pressure, systemic Vascular Resistance, Ease of Use, Adverse

Events, Termination from the study, and Definition of competitive cardiac

output technology.

Study description

Background summary

MASTERMIND
Performance Evaluation of Arterial Pressure Cardiac Output Systems as Compared

to Standard Thermodilution and other Alternative Cardiac Output Measurements.

Sponsor:
Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

The FloTrac Sensor is a less invasive hemodynamic monitoring device that, when used with the Vigileo monitor, measures continuous cardiac output (CCO) through an arterial pressure line.

Study objective

The purpose of this study is to evaluate accuracy of Cardiac Output measurements by comparing the Cardiac Output calculated by Arterial Pressure based Cardiac Output (APCO) and by other well accepted indicator dilution techniques, as well by competitive technology and devices (COCD).

Study design

This is a prospective, paired sample comparison study that will be conducted at various sites located throughout Europe.

Study burden and risks

No burden or risks considered associated with participation.
This will be an observation study.

Contacts

Public
Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
USA
Scientific
Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
USA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient must have an indwelling pulmonary artery catheter and either a radial or a femoral or other arterial catheter in order to participate in the study.
Patient will have the pulmonary artery catheter remain in-situ for a minimum of 8 hours after study initiation.
Patient is able to comply with the study procedure.
Patient, guardian or person authorized with power of attorney to give informed consent prior to placement of indwelling catheters according to applicable country specific law.
Patient must be 18 years old or older.
Ability to obtain an accurate subject height and weight prior to study start and as required during the study period.

Exclusion criteria

Patients with contraindications for the placement of radial, femoral or other arterial cannulae.
Patients with aortic valve regurgitation
Patients being treated with an intraaortic balloon pump.
Patients less than 40 kg in weight.
Pronounced cardiac arrhythmia (such as bigeminy).
Female patients of childbearing potential with a known pregnancy.
Any contraindications for the type of COCD being evaluated.
The subject is currently participating in an investigational drug or another device study that has not completed the primary endpoint or that clinically interferes with the study endpoints. (Note: Trials requiring extended follow-up for products that were investigational, but have since become commercially available are not considered investigational trials.)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL12988.058.06