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Comparison of different blood flow monitoring systems in critically ill patients

Submission date	Recruitment status	[_] Prospectively registered
30/11/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/12/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/01/2023	Circulatory System	

Plain English summary of protocol

Background and study aims
In critically ill patients it is important to closely monitor aspects of blood flow (haemodynamic parameters) such as amount of blood flow, the blood pressure, the heart output. The technique used to measure this is known as transpulmonary thermodilution and pulse contour analysis. The measurements can be performed using a tube attached to sensory equipment inserted into a large blood vessel (central venous catheter). Precise and reliable measurements are important. At the present time there are two devices which are routinely using transpulmonary thermodilution and pulse contour analysis to determine extended haemodynamic parameters: PiCCO and EV1000 monitoring systems. The aim of this study is to compare the PiCCO and EV1000 for neck vein (jugular) and leg vein (femoral) measurements.

Who can participate?
Patients aged 18 years or above who are being treated in the intensive care unit.

What does the study involve?
In this study EV1000 will be replaced by PiCCO device or vice-versa. During the exchange of these monitoring systems, measurements will be performed using the jugular and femoral central venous catheter to allow the comparison of both haemodynamic monitoring systems.

What are the possible benefits and risks of participating?
The measurements during the exchange from one to another monitoring system guarantee the reliability of determined parameters and its usefulness for further therapeutic management. As both systems are clinically approved and routinely used, there is no additional risk by the devices. The decision for exchange of arterial or central venous/shaldon catheter will be made irrespective of the study according to local standards. The most common complication of replacement of arterial or central venous line are vascular-, pulmonary-, cardiac-complications, catheter dysfunction or infection.

Where is the study run from?
Klinik und Poliklinik für Innere Medizin II am Klinikum rechts der Isar, Technische Universität München, Germany

When is the study starting and how long is it expected to run for?
January 2017 to March 2017

Who is funding the study?
Klinik und Poliklinik für Innere Medizin II am Klinikum rechts der Isar, Technische Universität München, Germany

Who is the main contact?
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The usefulness of transpulmonary thermodilution (TPTD) for the measurement of extended hemodynamic parameters (e.g. cardiac index (CI), global end-diastolic volume index (GEDVI), extra vascular lung water index (EVLWI), pulmonary vascular permeability index (PVPI) and global ejection fraction (GEF)) has been demonstrated in a number of studies. Usually TPTD is performed by indicator injection via the jugular or subclavian vein. However, under certain circumstances, superior vena cava access is not feasible. In these cases, femoral access can be used for measurement. Femoral Indicator bolus injections using PiCCO®-device have demonstrated significant overestimation particularly of GEDVI due to the additional volume of the inferior vena cava. This overestimation was corrected by formula and integrated in the newest algorithm used by PiCCO®-device. Recently, in addition to the PiCCO® device, another commercially available device for TPTD has been introduced, EV1000/VolumeView® which uses similar methodologies and algorithms as the PiCCO® device. However, there are no systematic data on the impact of femoral indicator injection for the EV-1000® device
Therefore, we compared the agreement of hemodynamic parameters sequentially derived by femoral as well as jugular indicator injection using the EV-1000® and the PiCCO® device in patients equipped with both jugular and femoral venous access.

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EV-1000

Study information

Scientific Title
Comparison of global end-diastolic volume index derived from jugular and femoral indicator injection in patients equipped with both a PiCCO-2 and an EV-1000-device

Study objectives
Are parameters derived by PiCCO and EV-1000-device comparable?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/06/2012, Ethikkommission; Fakultät für Medizin; Technische Universität München (Ismaninger Straße 22, 81675, München, Germany; +49 4140-7737; ethikkommission@mri.tum.de), ref: 5384/12

Study design
Prospective observational study

Primary study design

Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Critically ill patients with the need for extended hemodynamic monitoring

Interventions
First, only patients already equipped with a central venous catheter/dialysis catheter and PiCCO or EV-1000 monitoring system will be enrolled in this study.

Second, the treating physician (not involved in the study) performs the change of the CVC and the arterial line in patients with pre-existing and continuous need for advanced haemodynamic (transpulmonary thermodilution)-monitoring. This decision will be made irrespective of the study according to local standards. During the change of catheters, measurements with PiCCO- and EV-1000-device will be performed. A measurement consists of a triplicate injection of indicator (15 ml ice cold 0,9% saline solution). Duration of the measurement is around 15 minutes. There is no other intervention or follow up.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
PiCCO® device EV-1000® device

Primary outcome measure
Global end-diastolic volume (index) measured using PiCCO and EV1000

Secondary outcome measures
Measured using PiCCO and EV1000
1. Cardiac output/index
2. Cardiac function index
3. Global ejection fraction
4. Extravascular lung water index
5. Pulmonary vascular permeability index

6. Central venous pressure
7. Systolic volume variation
8. Pulse pressure variation

Overall study start date
01/08/2016

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Patients treated on the intensive care unit
2. Critically ill patients
3. Patients with the need of a change of CVC and arterial line in patients with pre-existing and continuing need for TPTD-monitoring
4. Hemodynamic stable patients without vasopressors or with a constant vasopressor-dosage

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10

Total final enrolment
10

Key exclusion criteria
1. Pregnant
2. Younger than 18 years old

Date of first enrolment
25/01/2017

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
Germany

Study participating centre
Klinikum rechts der Isar, Technische Universität München
Ismaningerstraße 22
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Sponsor information

Organisation
Klinikum der Universität München

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.frauenklinik.med.tum.de/

ROR
https://ror.org/02jet3w32

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Technische Universität München

Alternative Name(s)
Technical University of Munich, TUM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Germany

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/11/2020	17/01/2023	Yes	No