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Development of a warning system for circulatory instability in critically ill patients

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/02/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/02/2021	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol
Background and Study Aims
Monitoring Cardiac ouptut is essential to treat patients with shock in the intensive care unit. The aim of this study is to improve short term detection of changes in cardiac output by means of a software algorithm with data from pulmonary artery cathter

Who can participate?
Adult patients with shock and a pulmonary artery catheter at the University Hospital Bern (Switzerland)

What does the study involve?
This observational study only collects routinely collected data. No additional study-specific measures are taken

What are the possible benefits and risks of participating?
None

Where is the study run from?
University Hospital Bern (Switzerland)

When is the study starting and how long is it expected to run for?
October 2017 to December 2021

Who is funding the study?
Edwards Lifesciences (Switzerland)

Who is the main contact?
Dr David Berger, david.berger@insel.ch

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2018-00232

Study information

Scientific Title
Pulmonary artery pulse contour analysis in critically ill patients

Study objectives
The primary objective of this analysis is the evaluation of pulmonary artery pulse contour analysis to detect trends in cardiac output and pulmonary artery resistance and elastance. After establishing a routine for pulse contour analysis, respective stroke volumes will be compared with intermittent and continuous cardiac output.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/04/2018, Ethics Committee of the Swiss Canton of Bern (Kantonale Ethikkomission für die Forschung, Gesundheits- und Fürsorgerdirekton des Kanton Bern, Murtenstrasse 31, CH-3010 Bern
Switzerland; + 41 31 633 70 70; info.kek.kapa@gef.be.ch), ref: 2018-00232

Study design
Single center observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Shock

Interventions
Patients are eligible for the observational trial when they are monitored in the ICU by a pulmonary artery catheter. Hemodynamic data will be collected in real time for a period of 24 hours in addition to lab and clinical data. No specific interventions relate to the trial. The observation period is 24 hours maximum or until removal of the pulmonary artery catheter.

Intervention Type
Other

Primary outcome measure
Cardiac stroke volume measured using the pressure trace of the pulmonary artery collected using 24 hour ECG

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/10/2017

Completion date
31/12/2021

Eligibility

Key inclusion criteria
Adult patients (age >= 18 years) treated on the participating intensive care unit for shock of any etiology monitored with a pulmonary artery catheter are eligible for inclusion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,000

Key exclusion criteria
1. Patients/next of kin refusing to provide general consent
2. Mother tongue different from available general consent forms
3. Known pregnancy or breastfeeding
4. Patients institutionalized in correctional facilities
5. Patients institutionalized in psychiatric institutions

Date of first enrolment
08/06/2018

Date of final enrolment
21/12/2021

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Bern
Department of Intensive Care Medicine
Inselspital
Freiburgstrasse
Bern
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3010

Sponsor information

Organisation
Edwards Lifesciences (Switzerland)

Sponsor details

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Sponsor type
Industry

Website
http://www.edwards.com/ch-en

ROR
https://ror.org/012fexm34

Funder(s)

Funder type
Industry

Funder Name
Edwards Lifesciences

Alternative Name(s)
Edwards, Edwards Lifesciences Corporation, Edwards Lifesciences Corp., Edwards Lifesciences LLC, ELC

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

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

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date