

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

Submission date 27/01/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/02/2021	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and Study Aims

Monitoring Cardiac output 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 catheter

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

Dr David Berger

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

Protocol serial number

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 Ethikkommission für die Forschung, Gesundheits- und Fürsorgerdirektion 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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s))

There are no secondary outcome measures

Completion date

31/12/2021

Eligibility**Key inclusion criteria**

Adult patients (age \geq 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Switzerland

3010

Sponsor information

Organisation

Edwards Lifesciences (Switzerland)

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, E, ELC

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

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