

Safety and efficacy of cardiac output invasive monitoring in elderly patients

Submission date 30/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/07/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/10/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The optimal treatment for elderly patients with severe heart failure depends on accurate assessment and monitoring.

Pulse-induced contour cardiac output (PiCCO)-based hemodynamic monitoring is a relatively new technology.

This study aims to test the effect of using PiCCO monitoring or noninvasive hemodynamic monitoring on the length of hospital stay.

Who can participate?

Elderly patients with severe heart failure.

What does the study involve?

Between January 2016 and July 2020, patients were enrolled and assigned randomly to the PiCCO group or noninvasive hemodynamic monitoring group using a prospective observational study design. Hospital stay results were evaluated.

What are the possible benefits and risks of participating?

The PiCCO device might be more sensitive than non-invasive monitoring.

PiCCO has the risk of an invasive operation: bleeding, infection, and unsuccessful puncture.

Where is the study run from?

Chinese PLA general hospital (China)

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

January 2016 to July 2020

Who is funding the study?

Chinese PLA general hospital (China)

Who is the main contact?

Dr Hongwei Liu, qilipingping@163.com

Contact information

Type(s)

Scientific

Contact name

Dr Hongwei Liu

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Safety and efficacy of pulse-induced contour cardiac output monitoring in elderly patients with coronary artery disease and severe heart failure at coronary care units

Study objectives

Early invasive PiCCO monitoring is safe in critically ill elderly patients with severe heart failure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 30/12/2016, The Ethics Review Board of Chinese PLA General Hospital (#28 Fuxing Road, Haidian District, Beijing 100853, China; +86-010-66887329; no email provided), ref: 16BJZ22

Study design

Single center observational retrospective and prospective cohort study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Elderly patients with severe heart failure

Interventions

Between January 2016 and July 2020, 190 elderly patients with severe heart failure were enrolled and assigned randomly (using a random number generator) to the PiCCO group (89 patients) or noninvasive hemodynamic monitoring group (101 patients). Hospital stay results were evaluated. The participants were followed up for at least 1 year.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

PiCCO cardiac output monitor

Primary outcome(s)

Length of hospital stay measured using patient records at the end of the study

Key secondary outcome(s))

There are no secondary outcome measures

Completion date

31/07/2020

Eligibility

Key inclusion criteria

1. Known history of coronary heart disease
2. Orthopnea (inability to lie down)
3. Wet rales in the lungs
4. Edema in the lower extremities
5. Echocardiography showing left ventricular end-diastolic diameter of >50 mm and left ventricular ejection fraction(LVEF) of <50%, or chest X-ray showing pulmonary congestion or edema
6. Type I respiratory failure (partial pressure of oxygen of <50 mm Hg even after oxygen therapy, requiring tracheal intubation and mechanical ventilation after conventional treatments, such as cardiotonic therapy, diuretics, and vasoactive drugs).
7. Aged 65 - 100 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Total final enrolment

191

Key exclusion criteria

1. Heart failure
2. Uncontrolled severe infection, and pulmonary diseases

Date of first enrolment

01/01/2016

Date of final enrolment

31/07/2020

Locations**Countries of recruitment**

China

Study participating centre

Chinese PLA general hospital

28# Fuxing road

Haidian district

Beijing

China

100853

Sponsor information**Organisation**

Chinese PLA General Hospital

ROR

<https://ror.org/04gw3ra78>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Chinese PLA General Hospital

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/10/2022	25/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes