ISRCTN73335561 https://doi.org/10.1186/ISRCTN73335561

Safety and efficacy of cardiac output invasive monitoring in elderly patients

Submission date
30/06/2021

Recruitment status
No longer recruiting

Registration date
09/07/2021

Overall study status
Completed

Last Edited
25/10/2022

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

ORCID ID
http://orcid.org/0000-0002-4361-4155

Contact details
Chinese PLA General Hospital
28# Fuxing road
Haidian district
Beijng
China
100853
+86-010-66876349
qilipingping@163.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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 participant information sheet.

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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2016

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

Age group
Senior

Sex
Both

Target number of participants
191

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

Sponsor details
28# Fuxing road
Haidian district
Beijing
China
100853
+86-13811490651
liuhw928@sina.com

Sponsor type
Hospital/treatment centre

Website
http://www.301hospital.com.cn/en2012/web/Introduction.html

ROR
https://ror.org/04gw3ra78

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chinese PLA General Hospital

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
09/12/2022

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