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Early diagnosis of right ventricular dysfunction in high-risk cardiac surgery patients – a pilot study

Submission date 16/10/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/11/2026	**Overall study status** Ongoing	
Last Edited 04/11/2026	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims

During heart surgery under general anaesthesia, doctors routinely use a thin catheter placed into the pulmonary artery (the blood vessel leading from the heart to the lungs) to monitor how well the heart works. A newer version, the Swan-Ganz IQ catheter, has an additional sensor that also records pressure in the right ventricle (the right-hand pumping chamber of the heart). Very little is known about how well this works in everyday practice. This pilot study aims to find out whether the catheter can display good-quality pressure curves from the right ventricle and the pulmonary artery at the same time in patients whose right ventricle is not working well, and whether changes in these curves could help detect problems with the right side of the heart early.

Who can participate?

Adults over 18 years of age who are scheduled for heart surgery, in whom a pulmonary artery catheter is needed anyway, and whose right ventricle function has been shown to be reduced by ultrasound of the heart or by cardiac catheterisation. Patients cannot take part if the catheter cannot be used safely (for example, a blood clot in the right-hand chambers of the heart or an active infection of the tricuspid valve) or if they cannot give informed consent.

What does the study involve?

After signing the consent form, 25 patients will be included. After they are put to sleep for their operation, the Swan-Ganz IQ catheter will be placed in the usual way and connected to a monitor. The monitor records pressures and other heart measurements, including the oxygen level in mixed venous blood. Monitoring continues after the operation, usually for 48 to 72 hours. Blood lactate is measured only from blood samples taken as part of routine care; no extra blood samples are needed. All patients receive the same procedure; there is no comparison group. The information collected is used to judge whether the catheter works as intended and whether it is associated with changes in the oxygen level and blood lactate. Any complications are recorded.

What are the possible benefits and risks of participating?
The catheter is used in the same way as a standard pulmonary artery catheter, so no additional risks beyond those of a standard catheter are expected. Known possible complications of such catheters include heart rhythm disturbances and, very rarely, injury to the heart. There is no direct benefit expected for participants; the results may help improve monitoring of future patients.

Where is the study run from?
Department of Anaesthesiology, Resuscitation and Intensive Medicine, General University Hospital in Prague (Czech Republic)

When is the study starting and how long is it expected to run for?
January 2027 to July 2027

Who is funding the study?
General University Hospital in Prague and the Ministry of Health of the Czech Republic (Czech Republic)

Who is the main contact?
Dr Jan Kunstýř, jan.kunstyr@vfn.cz

Contact information

Type(s)
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Additional identifiers

Protocol/serial number
147/26 S-IV Grant

Study information

Scientific Title
Simultaneous right ventricular and pulmonary artery pressure waveform monitoring with the Swan-Ganz IQ catheter in adult cardiac surgery patients with right ventricular dysfunction: a single-centre, single-arm feasibility pilot study

Study objectives
1. To assess the technical feasibility of obtaining an adequate right ventricular (RV) pressure waveform together with a pulmonary artery waveform using the Swan-Ganz IQ catheter in cardiac surgery patients with RV dysfunction
2. To explore how changes in the RV pressure waveform relate to mixed venous oxygen saturation (SvO_2) and lactate
3. To record technical and clinical complications of catheter use

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/09/2026, Ethics Committee of the General University Hospital in Prague (Na Bojišti 1, Praha, 12808, Czech Republic; +420 224964131; eticka.komise@vfn.cz), ref: 147/26 S-IV Grant

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Right ventricular dysfunction in patients undergoing cardiac surgery

Interventions
Twenty-five adult patients with right ventricular dysfunction who are scheduled for cardiac surgery and in whom a pulmonary artery catheter is clinically indicated will be enrolled. After induction of general anaesthesia, a Swan-Ganz IQ catheter will be inserted through an introducer sheath into the pulmonary artery using the standard technique and connected to the HemoSphere Alta monitor. In patients undergoing pulmonary endarterectomy, the catheter will be positioned in a pulmonary artery branch while maintaining an interpretable RV pressure waveform; in other patients it will be advanced to the wedge position. RV pressures, RV cardiac output and index, RV end-diastolic pressure, the difference between early and late diastolic RV pressure, pulmonary artery pressures, SvO_2 and the Global Hypoperfusion Index will be recorded continuously. There is no control group and no randomisation. Data are recorded from catheter insertion until catheter removal (routinely at least 48 hours after surgery), for a maximum of 72 hours per participant. Until its purchase by the hospital is completed, the HemoSphere Alta monitor is provided to the hospital on loan by the device supplier under a loan agreement; Swan-Ganz IQ catheters are purchased by the hospital.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Swan-Ganz IQ pulmonary artery catheter (Edwards Lifesciences, model AIQSGF8) with HemoSphere Alta monitor

Primary outcome(s)
1. Technical success of catheter placement measured using proportion of patients in whom adequate right ventricular and pulmonary artery pressure waveforms are displayed simultaneously on the HemoSphere Alta monitor, as assessed by the inserting anaesthesiologist at catheter insertion after induction of general anaesthesia

Key secondary outcome(s)
1. Relationship between RV diastolic pressure waveform changes and SvO_2 and lactate measured using Pearson correlation (exploratory, no predefined threshold) of continuously recorded RV pressure parameters with continuously monitored SvO_2 and with blood lactate from routine blood gas samples (no additional sampling) at arrival from the operating theatre, then every 3 hours during the first 24 hours and every 6 hours thereafter in stable patients, until catheter removal

2. Technical and clinical complications measured using incidence of failed insertion, serious arrhythmia, perforation of the superior vena cava or cardiac chambers, cardiac tamponade and catheter dislodgement, based on clinical records at catheter removal (cumulative from insertion; maximum 72 hours)

Completion date
31/07/2027

Eligibility

Key inclusion criteria
1. Age over 18 years
2. Signed informed consent
3. Planned cardiac surgical procedure
4. Clinical indication for pulmonary artery catheter insertion
5. Right ventricular dysfunction confirmed by echocardiography or cardiac catheterisation

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Contraindication to pulmonary artery catheter insertion
2. Thrombus in the right ventricle or right atrium
3. Active tricuspid valve endocarditis
4. Inability to obtain informed consent

Date of first enrolment
04/01/2027

Date of final enrolment
30/06/2027

Locations

Countries of recruitment

Czech Republic

Study participating centre
General University Hospital in Prague, Department of Anaesthesiology, Resuscitation and Intensive Medicine
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Study participating centre
General University Hospital in Prague, 2nd Department of Surgery
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Sponsor information

Organisation
General University Hospital in Prague

Funder(s)

Funder type

Funder Name
Všeobecná Fakultní Nemocnice v Praze

Alternative Name(s)
General University Hospital in Prague, VFN

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
Czech Republic

Funder Name
Ministerstvo Zdravotnictví Ceské Republiky

Alternative Name(s)
Ministry of Health of the Czech Republic, MZCR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Czech Republic

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	01/09/2026	19/10/2026	No	No