STUDY DOCUMENT COVER PAGE

Official Study Title:
The Role of Swan–Ganz Catheter in Hemodynamic Resuscitation for Patients with Cardiogenic Shock due to Acute Myocardial Infarction

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Thang Pham Xuan
Emergency Center, BachMai Hospital

Sponsor:
Investigator-Initiated Study

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INFORMED CONSENT FORM (ICF)

I. GENERAL INFORMATION

Study Title:
A Study on the Role of the Swan–Ganz Catheter in Hemodynamic Resuscitation for Patients with Cardiogenic Shock due to Acute Myocardial Infarction.

Principal Investigator:
Thang Pham Xuan
Emergency Center, BachMai Hospital

Sponsoring Institution:
Hanoi Medical University

Sponsor:
Investigator-Initiated Study

Study Duration:
3 years

Study Site:
Emergency Center, Bach Mai Hospital

Participant Code:
_____

II. GREETING

Dear Sir/Madam,

Thank you for taking the time to participate in this interview.

My name is Thang Pham Xuan, and I am a clinical researcher currently working at the Emergency Center, Bach Mai Hospital.

I am conducting the study titled: “A Study on the Role of the Swan–Ganz Catheter in Hemodynamic Resuscitation for Patients with Cardiogenic Shock due to Acute Myocardial Infarction.”

Research Objectives:

- To describe the clinical and paraclinical characteristics of patients with cardiogenic shock due to AMI treated at Bach Mai Hospital between 2025 and 2027.

- To assess the effectiveness of goal-directed hemodynamic monitoring using the Swan–Ganz catheter and evaluate 30-day outcomes.
- To identify potential factors related to hemodynamic control and complications during Swan–Ganz catheter monitoring.

I have received comprehensive training on research procedures and ethical standards in clinical practice.

You (or the individual under your guardianship) are invited to participate in this study because you meet the following inclusion criteria:

- Age ≥ 18 years and agree to participate voluntarily.
- Diagnosed with cardiogenic shock due to AMI based on IABP SHOCK II criteria:
    - Systolic blood pressure <90 mmHg for at least 30 minutes or requiring vasopressors to maintain SBP >90 mmHg;
    - Evidence of end-organ hypoperfusion with at least one of the following:
        1. Altered mental status;
        2. Urine output < 30 mL/hour;
        3. Cold, mottled skin;
        4. Serum lactate > 2 mmol/L.

Your participation is entirely voluntary. You may withdraw from the study at any time without any consequences to your care, treatment, or entitlements. Regardless of your decision, we will continue to provide care according to Ministry of Health protocols.

I will provide you with full details about the study. If you have any questions during this discussion, please feel free to ask for clarification.

III. STUDY INFORMATION

1. Why is this study necessary?

Cardiogenic shock is one of the leading causes of mortality in modern clinical practice, most commonly resulting from acute myocardial infarction (AMI). Despite advances in diagnosis and treatment, the in-hospital mortality rate of cardiogenic shock remains high, ranging from 27% to 51%.

Hemodynamic monitoring using the pulmonary artery catheter (Swan–Ganz catheter), which allows for continuous measurement of cardiac output and other key parameters, is increasingly important in the management of cardiogenic shock. Early and appropriate intervention based on hemodynamic data may improve survival rates.

Therefore, this study aims to provide scientific evidence to optimize treatment strategies and improve in-hospital outcomes for patients with cardiogenic shock.

2. What will I or my dependent be required to do if I agree to participate?

If you agree to participate, we will request your cooperation in the following procedures:

- Initial Interview: At the time of ICU admission, we will collect baseline demographic and clinical data such as age, gender, past medical history, and presenting symptoms. We will try to complete this in a single interview, but if needed, a second interview may be conducted.
- Sample Collection: Laboratory tests and clinical samples will be collected as per routine monitoring and study protocol.
- Chart Review: We may retrospectively review your medical records to gather additional data relevant to the study.
- Follow-up at 30 Days: For patients who survive to 30 days post-admission, we ask that you return for a follow-up visit at Bach Mai Hospital. This visit is essential for collecting outcome data.

3. How many people will participate in this study?

Patients will be enrolled if they meet all the inclusion criteria:

Inclusion Criteria:

- Age ≥ 18 years and voluntary consent.
- Diagnosed with cardiogenic shock based on IABP SHOCK II (2012) criteria:
    - SBP < 90 mmHg for ≥30 minutes or requiring vasopressors;
    - Evidence of end-organ damage with one of the following:
        1. Altered consciousness;
        2. Urine output < 30 ml/hour;
        3. Cold, mottled skin;
        4. Lactate > 2 mmol/L.

Exclusion Criteria:

- Cellulitis at the catheter insertion site.
- Anatomic anomalies or prior radiation therapy to the neck.
- Coagulopathy (INR > 1.5 and/or platelet count < 50 G/L).
- End-stage chronic diseases (advanced cancer, late-stage HIV, bedbound >3 months, cirrhosis Child-Pugh C, dialysis-dependent CKD).
- Cardiac arrest or mechanical complications (e.g., ventricular wall rupture) before catheter insertion.
- Congenital heart disease or intracardiac shunts.
- Legal guardian or patient refusal.

Sample Size: The estimated number of participants is at least 108 patients meeting the inclusion criteria and undergoing Swan–Ganz catheterization.

4. What are the potential risks or disadvantages of participating in this study?

In patients who undergo Swan–Ganz catheterization, the following complications may occur:

A. Intra-procedural Complications:

- Catheter coiling in the right ventricle: May occur if the correct insertion depth is not maintained. If the catheter cannot be advanced to the pulmonary artery, it should be withdrawn slightly before re-advancing.
- Bleeding: Managed by local compression or referred to vascular surgery if needed.
- Pneumothorax: Managed with pleural drainage as indicated.
- Cardiac arrhythmias: Treated based on the specific rhythm disorder encountered.

B. Post-procedural Complications:

- Failure to deflate the balloon: After measuring the pulmonary artery occlusion pressure (PAOP), the balloon must be deflated to prevent complications.

C. Delayed Complications:

- Infection at the catheter insertion site: Requires removal of the catheter and appropriate antibiotic therapy.
- Obstruction of the catheter lumen: May require catheter replacement or removal.

5. What care will be provided if any harm or adverse effects occur?

All Swan–Ganz catheter placements will strictly adhere to the standard procedure as regulated by the Ministry of Health and institutional protocols (e.g., Decision No. 2538 by Bach Mai Hospital).

Each complication, if it arises, will be addressed according to established clinical guidelines and individual case assessment.

6. What benefits can I or my dependent expect from participating?

- All participants will receive structured health monitoring and free follow-up consultations as per the study schedule.
- At any time during participation, if you require health advice, the research team will provide prompt, detailed, and appropriate support.

While direct benefits to you may be limited, the information obtained from this study could help improve treatment protocols for future patients with similar conditions.

7. If I choose not to participate, will I still receive proper treatment?

Yes. Patients who do not agree to participate in the study will still be treated according to the national clinical guidelines for cardiogenic shock, as defined by the Ministry of Health.

There will be no difference in the treatment regimens provided to participants and non-participants. Participation in Swan–Ganz catheter monitoring is entirely voluntary, and refusal will not affect the care or benefits you receive.

8. How will my personal and medical information be kept confidential?

All records and personal information related to this study will be securely stored and managed according to the regulations of Bach Mai Hospital and the Ministry of Health.

Access to research data will only be granted with formal institutional approval. Your identity will be protected, and your data will not appear in any publications or reports.

9. Who should I contact for more information?

Principal Investigator:

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- Hanoi Medical University
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Study Site:

- BachMai Hospital
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Institutional Review Board (IRB):

- BachMai Hospital
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IV. VOLUNTARY CONSENT FORM

I, the undersigned, hereby confirm the following:

- I have read the information sheet for the study titled:
  “A Study on the Role of the Swan–Ganz Catheter in Hemodynamic Resuscitation for Patients with Cardiogenic Shock due to Acute Myocardial Infarction”
  Conducted at Bach Mai Hospital, ICF version 01, dated May 21, 2025, and I have received a clear explanation of this research and its registration procedures from the research team.
- I have had the opportunity to ask questions and have received satisfactory answers and explanations.
- I have been given sufficient time and opportunity to consider my decision to participate.
- I understand that I have the right to access my data, as described in the information sheet.
- I understand that I may withdraw from the study at any time, for any reason, without needing to provide justification.
- I agree that my primary healthcare provider (if any) may be informed of my participation in this study.

Please mark the appropriate box:
☐ Yes ☐ No (Yes: I voluntarily agree to participate in this research study).

Participant’s Full Name and Signature
(or Guardian’s Full Name and Signature if the participant is a minor or lacks decision-making capacity)
.....
Date: …… / …… / 202…..

If applicable:

Witness’s Full Name and Signature
.....
Date: …… / …… / 202…..

Researcher’s Full Name and Signature
.....
Date: …… / …… / 202…..