The Effect of Intra Aortic Balloon Pump Early Insertion on Mortality in Post Cardiac Arrest Patients with Acute Coronary Syndrome

Date: 23th October 2017

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Study Protocol

Title

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Principal Investigator

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Sponsor

Indonesia University

Aim

To observe the effects of intra aortic balloon pump on clinical outcomes of cardiac arrest patients and prognosis improvement through circulation and tissue perfusion improvement.

Study Design

Randomized clinical trial.

Anticipated Outcome

Early insertion of intra aortic balloon pump will be improving in-hospital mortality rate of cardiac arrest patients with acute coronary syndrome.

Inclusion and Exclusion Criteria

Inclusion Criteria

1. Cardiac arrest survivor patients with acute coronary syndrome
2. Age over 18 years and less than 75 years

Exclusion Criteria

1. History of stroke based on anamnesis
2. Unequal pupil
3. History of previous inta aortic balloon pump usage
4. Aortic regurgitation
5. Brugada and congenital long QT syndrome

Withdrawal or Discontinuation Criteria

1. Patient dies prior to intra aortic balloon pump insertion
2. Treatment termination requasted by family
3. Anemia due to hemorrhage with a decrease in Hb> 3 g / dL
4. Ankle brachial index (ABI) less than 0.8

Procedures

1. Patients who meet the criteria and agree to participate in the study taken as the subject of the research.
2. Research subjects were then randomized into two groups. The control group (Group A) and the treatment group (Group B) as the group that receiving intra aortic balloon pump (IABP) as early as possible within 3 hours after the return of spontaneous circulation (ROSC). IABP insertion is performed by an interventionist.
3. Baseline data such as age, weight, height, risk factor (hypertension, Diabetes Mellitus,

dyslipidemia, smoking, family history), history of Acute Myocardial Infarct (AMI), Percutaneous Coronary Intervention (PCI), Coronary Artery Bypass Graft (CABG), and valvular disease will be taken. Vital signs examination and EKG 12 leads will be performed.

- Laboratory tests for peripheral venous blood include: Lactate levels, urea (Ur), creatinine (Cr), n-terminal pro B-type natriuretic peptide (NT Pro BNP), high sensitive troponin (Hs Trop), IL-6, beclin 1 and caspase 3.
- Central venous blood examination for central venous blood gas analysis includes assessment of a-vO2 diff and ScvO2.
- Arterial blood examination for arterial blood gas analysis.

Monitoring of hemodynamic parameters using echocardiography machines (ejection fraction, TAPSE, cardiac output, VTI).

4. In the group B, IABP is initiated within 3 hours after the return of spontaneous circulation by the interventionist.
5. Blood sampling is repeated at 6th hour post ROSC or 1 hour post-insertion of IABP consisting of:

- Laboratory tests for peripheral venous blood include lactate, IL-6, beclin-1 and caspase 3 levels.
- Central venous blood examination for central venous blood gas analysis includes assessment of a-vO2 diff and ScvO2.
- Arterial blood examination for arterial blood gas analysis.

Examination of hemodynamic parameters with echocardiographic machine was repeated at the 6th hour post ROSC, consisting of ejection fraction, TAPSE, cardiac output, VTI).

6. Research subjects will be monitored during hospitalization.

Analysis Method

Data analysis using SPSS 20.0 software program with appropriate statistical test. Data taken during the study will be displayed according to the variable type. Numerical variables with normal distribution will be displayed as mean ± standard deviation, which is then analyzed by a general linear model (GLM) test for data measured more than once (IL-6, Beclin-1, Caspase-3, a- vO2 diff, and ScvO2) and independent t test for data with one time measurement (mortality rate in hospital and effective lactate clearance). Numerical variables with abnormal distribution will be shown in median (minimum-maximum) and then analyzed by Mann-Whitney test. The categorical variable will be displayed as a percentage (number) and will be analyzed by chi-square test or alternate test.

Treatment Duration

During hospitalization

Primary Outcome

In-hospital mortality

SUBJECT INFORMATION AND CONSENT FORM

The study aim to observe the effect of Intra Aortic Ballon Pump (IABP) early insertion on mortality of post cardiac arrest patient with acute coronary syndrome in National Cardiovascular Center Harapan Kita Hospital.

102 individuals will be enrolled in the study. The duration of participation of each subject is during the hospitalisation.

A. Participation in the research

You are free to participate in this study without any coercion. Once you have decided to participate, you are also free to resign / change your mind at any time without any penalty. If you refuse to participate then the patient will still be treated according to hospital procedures.

B. Research Procedures

1. Patient personal data and history will be taken: name, age, history of disease, smoking and family history.
2. Physical examination will be performed to obtain vital signs and urine production.
3. At 30 minutes after the return of spontaneous circulation, peripheral blood sampling will be done as much as 12 ml for laboratory examination of various clinical indicators.
4. Echocardiography examination will also be done to determine the patient's hemodynamic status.
5. If the patient is receiving IABP, the insertion will be done in 3 hours after the return of spontaeous circulation by an interventionalist.
6. At 6 hours after the return of spontaneous circulation, peripheral blood sampling will be done for the second time. Echocardiography examination will also be performed.
7. The patient's condition and progress will be monitored during hospitalization

C. Risks and Side Effects

Complications that may occur in the intra-aortic balloon pump insertion including blood vessel-related complications such as angio-ischemia, thrombocytopenia, infection, tearing of the aortic vessels, renal failure, neurological disorders, and bleeding. Studies show a complication of limb ischemia of less than 1%. Bleeding occurred in 0.8% of cases. If acute limb ischemia is occured, duplex evaluation and the removal of intra-aortic balloon pump will be done continued with fibrinolytic therapy or thrombus transcatheter aspiration.

D. Benefits

This study will prove the benefit of the intra-aortic balloon pump early insertion in improving the prognosis of cardiac arrest patients, therefore increase the life expectancy of cardiac arrest survivor.

E. Confidentiality

All information relating to the study will be kept confidential and will be known only to researchers and research staff. The results of the study will be published without the identity of the study subjects.

F. Financing

All research related costs will be borne by researchers and National Cardiovascular Center Harapan Kita Hospital.

G. Additional Information

If at any time further explanations are needed, you can contact Isman Firdaus, MD at ICVCU National Cardiovascular Center Harapan Kita Hospital.
You can also inquire the information about the research from the Research Ethics Committee of National Cardiovascular Center Harapan Kita Hospital, Phone +62-5681111, ext. 2837/2831 or email: irb.kometik_rsjpdhk@gmail.com.

SUBJECT INFORMATION AND CONSENT FORM

Name :

Age :

Gender :

Address :

ID number :

As myself / husband / wife / child / parent / sibling * of:

Name :

Date of birth :

Gender :

Address :

With this stated AGREE to participate in the study. The purpose, nature, benefits of this study, and the risks it may cause has been adequately explained by the physician / researcher and I have fully understood.
This consent I make with full consciousness and without coercion.

Signature : _____

Date : _____

*cross the unnecessary ones