Clinical Effects of Intra-aortic Balloon Support in Early Acute Coronary Syndrome and non-Acute Coronary Syndrome related Cardiogenic Shock: a Multicenter Randomized Controlled Trial

Published: 28-05-2024
Last updated: 30-01-2025

The aim of this randomized trial is to appraise the impact of IABP in the treatment of early stages of cardiogenic shock, irrespective of etiology. Findings of this randomized trial may enhance clinical decision making regarding the use of MCS in...

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON56763

Source
ToetsingOnline

Brief title
IABP ON-TIME

Condition

- Heart failures
- Cardiac therapeutic procedures

Synonym
(non-) ischemic cardiogenic shock, Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Arrow/Teleflex Inc.,Bedrijven (Arrow/Teleflex Inc.)

Intervention

Keyword: - Intra-aortic balloon pump, - Ischemic cardiogenic shock, - Mechanical circulatory support, - Non-ischemic cardiogenic shock

Outcome measures

Primary outcome

The primary endpoint of the trial is a composite of 1) all-cause mortality; 2) escalation to invasive mechanical ventilation; 3) escalation of MCS (including institution of IABP support in the standard of care-arm, or escalation to continuous flow or extracorporeal MCS); 4) acute kidney injury and 5) stroke or transient ischemic attack, at 30 days.

Secondary outcome

Secondary outcomes include at 1 year 1) all-cause mortality and 2) unplanned hospital re-admission for cardiovascular causes.

The following secondary trial endpoints will also be investigated throughout the trial (at 30-day follow-up, if not specified otherwise):

- The individual determinants of the composite primary outcome.

- Treatment escalation (see chapter 8 of the IABP ON-TIME protocol, version 2.0).

- Deterioration of cardiogenic shock.

- Vascular complications following randomization to the IABP-arm.

- Major bleeding complications following randomization to the IABP-arm.

- De novo Acute Coronary Syndrome (ACS) (i.e. type 1 Myocardial Infarction)

both at 30-days and 1-year follow-up.

- Cardiopulmonary resuscitation or defibrillation.

- The development of Systemic Inflammatory Response Syndrome (SIRS), sepsis or

severe sepsis within 96 hours after randomization.

Study description

Background summary

The scientific underpinning for the use of mechanical circulatory support (MCS) in early cardiogenic shock, especially for the intra-aortic balloon pump (IABP), is scarce and insufficiently clarified for different etiologies of cardiogenic shock. Previous randomized trials limited the inclusion criteria to patients with ischemic cardiogenic shock while observational research suggested favorable effects of timely adoption of IABP in patients with deteriorating myocardial function through ischemic or non-ischemic causes. Early stage of cardiogenic shock is defined by relative hypotension without hypoperfusion, or hypoperfusion still responsive to therapy (Society for Cardiovascular Angiography and Interventions, SCAI, stage B and C, respectively). A tightening of global guidelines with respect to the clinical adoption of IABP overshadowed the potential beneficial effects for specific patient categories within the total spectrum of cardiogenic shock. Patients currently presenting with early stages of cardiogenic shock caused by ischemic or non-ischemic etiology are hypothetically undertreated due to an assumed lack of clinical benefit of IABP in general.

Study objective

The aim of this randomized trial is to appraise the impact of IABP in the treatment of early stages of cardiogenic shock, irrespective of etiology. Findings of this randomized trial may enhance clinical decision making regarding the use of MCS in specific subsets of patients in early stages of cardiogenic shock.

Study design

Open-label, multicenter, investigator-initiated, randomized controlled trial.

Intervention

Patients enrolled in this trial will be 1:1 randomized to IABP support or standard of care (i.e. inotropes and/or vasopressors but no IABP insertion). Patients will be stratified for ACS/non-ischemic etiology and stage B/stage C cardiogenic shock following stratification according to center.

Study burden and risks

The risk profile attributable to trial participation (moderate, in Dutch 'matig') is acceptable given the reported low complication rate directly attributable to IABP insertion (according to earlier research). If randomized to the IABP-arm, an IABP will be inserted after transfemoral arterial access (the patient is prescribed bedrest afterwards). Apart from this, trial participation does not involve any specific treatment, test or rule of conduct (e.g. during follow-up). Findings of this randomized trial will attribute to future patient selection for MCS within the full spectrum of cardiogenic shock as well as to verify and to strengthen current clinical guidelines. The trial may shed further light to treatment differences for patients in different (cardiogenic) shock stages.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- At least 18 years of age.
- Society for Cardiovascular Angiography and Interventions (SCAI) stage B or C cardiogenic shock. For definitions, please see chapter 4 of the IABP ON-TIME protocol (version 2.0).
- No more than 1 inotropic agent has been administered and the maximum dose of noradrenaline/norepinephrine has not exceeded 0.2 µg/kg/min at the time of randomization to reach mean arterial pressure >65 mmHg.

Exclusion criteria

- Patient in cardiogenic shock, not fulfilling the definition for SCAI stage B or C. For definitions, please see chapter 4 of the IABP ON-TIME protocol (version 2.0).
- Administration of >=2 inotropic or vasopressive agents at the time of randomization.
- Administration of noradrenaline/norepinephrine exceeding 0.2 µg/kg/min at the time of randomization.
- Suspected or known mechanical complication contributing to cardiogenic shock, e.g. ventricular septal defect or papillary muscle rupture.
- Cardiogenic shock developing within 72 hours of a surgical procedure (i.e. low cardiac output with an inability to wean cardiopulmonary bypass).
- Inability to provide informed consent. Of note: patients admitted in cardiogenic shock who required cardiopulmonary resuscitation earlier, but are conscious at the time of hospital admission, are eligible for study participation.
- Known or suspected insufficiency of the aortic valve with at least moderate aortic regurgitation.
- Known or suspected peripheral arterial disease preventing safe insertion of IABP.
- Known or suspected thoracic or abdominal aortic disease (including aortic dissection or aortic aneurysm) precluding safe insertion and use of IABP.
- Suspicion of sepsis or septic shock (including septic cardiomyopathy).
- Pregnancy.
- Predicted life expectancy <6 months because of concomitant disease.

- Concurrent participation in a clinical trial with competing endpoints.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2024
Enrollment:	250
Type:	Anticipated

Ethics review

Approved WMO Date:	28-05-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-01-2025
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	De studie wordt momenteel geregistreerd op clinicaltrials.gov: het referentienummer is op dit moment nog niet beschikbaar.
CCMO	NL85563.078.24