Impella®-Supported PCI in High-Risk Patients With Complex Coronary Artery Disease and Reduced Left Ventricular Function

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 90 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Age ≥18 years and ≤90 years 2. Clinical presentation and baseline left ventricular function are as follows: Either 2A or 2B must be present A. Subject has CCS or NSTEMI with an LVEF ≤40% NOTE: The LVEF must be quantitatively measured as ≤40% by echo within 30 days assuming no change in clinical condition. If multiple echos have been performed within 30-days, the most recent test must be used to qualify the patient. NOTE: Subject qualifies if the quantitative site read LVEF is ≤30%; if the quantitative site read is \>30%

•≤40% the Echo Core Lab must confirm the LVEF is ≤40% before subject enrollment (Core Lab will provide \<48-hour turnaround). Similarly, if the site read is qualitative only (i.e., only provides broad ranges without detailed LVEF quantification), the Echo Core Lab must confirm the LVEF is ≤40% before subject enrollment. OR B. Subject has STEMI ≥24 hours and \<30 days after symptom onset with an LVEF ≤30% NOTE: In patients qualifying with recent STEMI, the LVEF must be demonstrated to be ≤30% by quantitative echocardiography after the primary PCI procedure (if performed) and within 72-hours prior to the planned randomization. If primary PCI was not performed, the qualifying echocardiogram will be the one taken during the index hospitalization closest to the index procedure. If the site read is qualitative only (i.e., only provides broad ranges without detailed LVEF quantification), the Echo Core Lab must confirm the LVEF is ≤30% before subject enrollment. 3. Local heart team (interventional cardiologist and cardiac surgeon) has determined that PCI is indicated and is the most appropriate management for the patient 4. Complex PCI will be performed: Either 4A or 4B must be met A. One of the following must be present: i. Triple vessel disease is present (visually-assessed angiographic DS ≥80% \[or ≥40% if non-invasive evidence of ischemia on a localizing stress test or invasive evidence of ischemia (FFR ≤0.80 or iFR ≤0.89)\] is present in all 3 epicardial coronary artery distributions in a main vessel or branch with visually-assessed reference vessel diameter ≥2.5 mm) with PCI planned in ≥2 of these vessels in the proximal or mid LAD, proximal or mid-LCX or proximal, mid- or distal RCA \[i.e., not a branch vessel\]) OR ii. Left main distal bifurcation or trifurcation disease (visually-assessed DS ≥50% \[or DS ≥30% if non-invasive evidence of ischemia in both the anterior and posterolateral distributions or left main IVUS MLA ≤6.0 mm2 or FFR ≤0.80 or iFR ≤0.89\] is present) with planned intervention of the left main plus at least 2 branch vessels (i.e., the ostial LAD, ostial LCX or ostial ramus) OR iii. Left main equivalent disease with both ostial LAD and ostial LCX having visually-assessed angiographic DS ≥80% \[or ≥40% if non-invasive evidence of ischemia on a localizing stress test or invasive evidence of ischemia (FFR ≤0.80 or iFR ≤0.89\] and requiring intervention in both branches OR iv. Intervention of the last remaining vessel (native coronary artery or bypass graft) OR B. Multivessel disease is present (visually-assessed angiographic DS ≥80% \[or ≥40% if non-invasive or invasive evidence of ischemia is present\] in ≥2 of the 3 epicardial coronary artery distributions in a main vessel or branch with visually-assessed reference vessel diameter ≥2.5 mm) and PCI is planned of at least 2 separate complex lesions in main vessels or branch vessels each having one or more of the following characteristics: i. Long lesion (≥28 mm visually assessed) requiring ≥30 mm stent length (single or multiple) ii. Severe angiographic calcification (see Protocol definition) or requiring atheroablation iii. Any left main morphology not in Criterion A requiring intervention (e.g., isolated ostial or mid-shaft left main lesion or distal left main bifurcation lesion with a planned single provisional stent technique) iv. Non-left main bifurcation lesion requiring intervention in both the main branch and side branch v. CTO (TIMI 0 Flow) vi. Giant thrombus (length ≥3x vessel diameter) vii. SVG (other than focal (\<5 mm) disease of the proximal or distal anastomosis or in-stent restenosis) NOTES: 1. The multiple lesions can be in the same vessel if separated by ≥10 mm

•however, each separate lesion has to have one or more of the above characteristics 2. PCI may be performed on additional non-qualifying lesions (i.e., without 1 or more of the above high-risk characteristics) as long as there are at least two lesions also undergoing PCI with each having 1 or more of the above characteristics) 3. There are 2 exceptions to the rule that each separate lesion must have one or more of the above characteristics (as in Inclusion Criterion 4B above): The subject may qualify if undergoing complex PCI of a single lesion that has 2 or more of the above complex characteristics (as in Inclusion Criterion 4B above) if also: i. There is a CTO of a proximal or mid-LAD, proximal or mid-LCX or proximal, mid- or distal RCA (i.e., not a branch vessel) that will not be treated OR ii. The subject qualifies with recent STEMI with an LVEF ≤30% and the complex PCI is planned in a non-infarct vessel (i.e., a complex PCI in the infarct vessel does not qualify) 5. Subject or legal guardian (permitted at US sites only) agrees to randomization and to follow all study procedures and provides informed, written consent

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Exclusion Criteria:

Subjects must not meet ANY of the following Exclusion Criteria to participate in the Trial: 1. STEMI ≤24 hours from the onset of ischemic symptoms or at any time if mechanical complications of transmural infarction are present (e.g., VSD, papillary muscle rupture, etc.) 2. Cardiogenic shock (SBP \<80 mmHg for ≥30 mins and not responsive to intravenous fluids or hemodynamic deterioration for any duration requiring pressors or mechanical circulatory support, including IABP) 3. Subject is presently or recently intubated for the current admission (NOTE: recently intubated patients must be extubated for \>24 hours with full neurologic recovery) 4. Cardiorespiratory arrest related to the current admission unless subject is extubated for \>24 hours with full neurologic recovery and hemodynamically stable 5. Any contraindication or inability to Impella placement in both the left and right common femoral artery based on clinical or imaging findings, including iliofemoral artery diameter \<5 mm, tortuous vascular anatomy or severe bilateral peripheral vascular disease of the iliac or femoral arteries that can't be adequately treated (e.g., with intravascular lithotripsy) NOTES: 1. Computed tomography (CT), magnetic resonance angiography (MRA) or contrast angiography to assess the aorta and iliofemoral vasculature to ensure Impella compatibility must be performed within 90 days prior to randomization. It is recommended that this evaluation be performed prior to the index procedure. Absent a qualifying pre-procedure imaging study, contrast angiography of the potential Impella access vessel(s) must be performed in the Cath Lab before the planned enrollment after which the subject may be randomized if he/she still qualifies. Of note, if pre-procedure imaging was performed and after this test but before randomization there was a worsening in PVD symptoms, repeat imaging must be performed prior to randomization. 2. If iliofemoral peripheral vascular disease is present precluding Impella use that can be adequately treated with angioplasty, atherectomy or lithotripsy (without a stent), the subject can be enrolled if such treatment is undertaken and is successful and uncomplicated

•randomization must not be performed until such successful and uncomplicated treatment 6. Iliofemoral stents placed within 6 months of enrollment with planned vascular access through these vascular segments 7. Vascular access for Impella is required in any location other than the left or right common femoral artery (i.e., axillary access, transcaval access, etc., for Impella access are not permitted) 8. Known left ventricular thrombus 9. Incessant ventricular arrhythmias that would likely preclude stable Impella positioning 10. Severe aortic stenosis or severe aortic insufficiency 11. Prior mechanical valve or self-expanding TAVR (NOTE: prior bioprosthetic surgical valve or balloon expandable TAVR implanted \>24 hours pre-procedure is acceptable) 12. Prior CABG within three (3) months or successful prior PCI of at least one (1) attempted lesion within 12 months (including during the index hospitalization prior to randomization), that has not experienced stent thrombosis or restenosis during that 12-month period; the one (1) exception is that patients may be enrolled if a primary PCI for STEMI was performed during the index hospitalization without MCS and that was ≥24 hours and \<30 days prior to randomization. NOTE: Successful PCI for this exclusion criterion is defined as a visually-assessed angiographic DS ≤50% in at least one (1) attempted lesion. 13. Prior placement of IABP, Impella or any other MCS device for any reason during the index admission, prior to randomization 14. Known severe pulmonary hypertension (right ventricular systolic pressure (RVSP) on echo or pulmonary artery systolic pressure (PASP) on right heart

randomization 14. Known severe pulmonary hypertension (right ventricular systolic pressure (RVSP) on echo or pulmonary artery systolic pressure (PASP) on right heart catheterization) \>70 mm Hg unless active vasodilator therapy in the Cath Lab is able to reduce the pulmonary vascular resistance (PVR) to \<3 Wood Units or between 3 and 4.5 Wood Units with v-wave less than twice the mean of the pulmonary capillary wedge pressure 15. Symptoms or signs of severe RV dysfunction, such as anasarca (NOTE: Leg edema alone does not necessarily indicate severe RV dysfunction if the investigator believes it is due to LV dysfunction) 16. Severe tricuspid insufficiency 17. Platelet count \<75,000 cells/mm3, bleeding diathesis or active bleeding, coagulopathy or unwilling to receive blood transfusions 18. On dialysis 19. Prior stroke with any permanent neurologic deficit within the previous three (3) months, or any prior intracranial hemorrhage or any prior subdural hematoma or known intracranial pathology pre-disposing to intracranial bleeding, such as an arteriovenous malformation or mass 20. Taking a chronic oral anticoagulant that cannot be safely discontinued for at least 72-hours before and 72-hours after the index procedure (if a vitamin K antagonist) or that cannot be safely discontinued for at least 48 hours before and 48 hours after the index procedure (for a direct acting oral anticoagulant) 21. Plan for any surgery within 6 months necessitating discontinuing antiplatelet agents 22. Pregnant or child-bearing potential unless negative pregnancy test within 1 week 23. Participation in the active treatment or follow-up phase of another clinical study of an investigational drug or device that has not reached its primary endpoint 24. Any medical or psychiatric condition such as dementia, alcoholism or substance abuse which may preclude informed consent or interfere with any of the study procedures, including follow-up visits 25. Any non-cardiac condition with life expectancy \<3 years (e.g., cirrhosis, oxygen or oral steroid dependent COPD, cancer not in remission, etc.) 26. Subject is currently hospitalized for definite or suspected COVID-19 27. Subject has previously been symptomatic with or hospitalized for COVID-19 unless he/she has been discharged (if hospitalized) and asymptomatic for ≥4 weeks and has returned to his/her prior baseline (pre-COVID) clinical condition 28. Subject is asymptomatic (never ill) and COVID-19 PCR/antigen test is positive within the prior four (4) weeks unless a) subject remains asymptomatic for ≥2 weeks after the last positive test or b) the positive test occurred within six (6) months after the subject received a COVID vaccine 29. Subject belongs to a vulnerable population (defined as individuals with mental disability, impoverished persons, homeless persons, nomads, refugees and those permanently incapable of giving informed consent; vulnerable populations also may include members of a group with a hierarchical structure such as university students, subordinate hospital and laboratory personnel, employees of the Sponsor, members of the armed forces and persons kept in detention)

Conditions & Interventions

Interventions:
DEVICE: Impella CP® / Impella CP® with SmartAssist® / Impella 2.5®, DEVICE: IABP Intra-aortic balloon pump
Conditions:
Left Ventricular Dysfunction, Coronary Artery Disease
Keywords:
Non-ST Elevated Myocardial Infarction, Cardiovascular Diseases, Heart Diseases, Myocardial Ischemia, Myocardial Infarction, Anterior Wall Myocardial Infarction, Inferior Wall Myocardial Infarction

More Information

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Principal Investigator:
Phase: NA
IRB
Number: Pending IRB#
System ID: NCT04763200
