Randomization in Cardiogenic Shock is Challenging for Ethical & Logistical Reasons Without Exception From Informed Consent (EFIC)

Abiomed-Funded Randomized Controlled Trials (RCTs) with Impella® in Cardiogenic Shock

Study	Trial ID	Condition	Pts Required (n)	Pts Enrolled (n)	Duration (months)	Status	Discontinuation Reason/ comment
FRENCH TRIAL (2006)	NCT00314847	AMI CS	200	19	52	Discontinued	Low Enrollment
ISAR-SHOCK (2006) *Single Center in Germany*	NCT00417378	AMI CS	26	26 (13 Impella)	19	Completed; Met Primary Endpoint	Non-Randomized Execution; Cardiac Output Study
IMPRESS in STEMI (2007) *European Study*	NTR1079 trialregister.nl	STEMI Pre-CS	130	21	42	Discontinued	Low Enrollment; 1 Site Enrolled
RECOVER II FDA (2008) *Impella Pre-PCI Insertion*	NCT00972270	AMI CS	384	1	18	Discontinued	Low Enrollment; 50 US Sites
RELIEF I (2010)	NCT01185691	ADHF CS	20	1	33	Discontinued	Low Enrollment
IMPRESS in Severe Shock / Cardiac Arrest (2016) *Single Center European Study*	NTR3450	Cardiac Arrest w/ Mechanical Ventilation	Not Specified	48 (24 Impella; 5 Pre-PCI)	52	Discontinued	Low Enrollment; Non-Randomized or Sequential Execution
DanGer SHOCK (2012)	NCT01633502	AMI CS	360	>250	>100	Enrolling	Ongoing; Pre & Post-PCI Implantation
RECOVER IV FDA (2023) ***Impella Pre-PCI Insertion***	**NCT05506449**	**AMI CS**	**560**	**0**	**TBD**	**FDA IDE Approved w/EFIC**	**Initial Planning**

As of September 12, 2022