What is the study device?

The heart pump being studied is the Impella CP®. This pump has been approved by the US Food and Drug Administration for use in patients with heart shock. The heart pump is inserted into the leg blood vessel through a thin tube and advanced through the blood vessel into the main pumping chamber of the heart.

Who is included in the study?

We will enroll eligible patients between the ages of 18–90 who come to a participating hospital with a heart attack and shock. Patients who meet study entry criteria will be randomly placed into 1 of 2 groups. Everyone will receive standard care treatment.

- Half will receive standard treatment for heart shock with the Impella CP® heart pump.
- The other half will receive standard treatment for heart shock without the Impella CP® heart pump.

What happens in the study?

Patients who receive the Impella CP® heart pump will have it placed for at least 24 hours. It will be removed when their doctor thinks it is appropriate to do so. Eligible patients who do not receive the heart pump will receive other standard treatments. Doctors may use other devices they think are needed. All study participants will be monitored in the hospital and for 1 year after their heart shock treatment.

What are the risks ?

There are known potential side effects of the Impella CP® including, but not limited to death, bleeding, stroke, infection, heart rhythm problems, damage to blood cells or heart tissues, liver failure and kidney failure. A risk specific to this study is damage to the heart due to delaying treatment while the Impella CP® is being placed.

What are the benefits ?

Observational studies and small, randomized trials suggest that the use of the Impella CP® might lead to better outcomes in patients with heart attacks and heart shock. A large, randomized trial is needed to know if the Impella CP® device is responsible for the improvement observed.

What is unique about the RECOVER IV study?

RECOVER IV will take place during medical emergencies. The window of time to perform treatment is short - Usually, about 60 minutes within hospital arrival. Patients may be too sick to make decisions, and a loved one may not be available to speak on their behalf. Because of this, some patients may be enrolled in the study before they can give consent. This is called “Exception from Informed Consent.”

How can people be enrolled in a study before they can give permission?

Special research rules allow emergency medicine studies, like RECOVER IV, to enroll a person into a study before they can give their consent when:

- The person's life is at risk,
- The best treatment is unknown,
- The person might benefit from the study, AND
- The person or their loved one cannot give consent.

Will the study team attempt to obtain consent?

The study team will attempt to obtain consent from eligible patients or their legal representatives. If this is not possible, we will give any immediately available family member an opportunity to object to enrollment. If we learn of any objection to participating in this research before the treatment begins, the patient will not be included in RECOVER IV.

If a patient is enrolled before they can give consent, we will notify the patient, family member, or legal representative, as soon as possible.

Which hospitals will participate in the study?

You can learn about participating U.S. hospitals at **https://bit.ly/R4Sites**

What if I don't want to participate?

If you do not want to be enrolled in RECOVER IV, you can choose to opt-out before you have a heart attack by contacting the RECOVER IV team. You will receive a silicone wristband with the words: "NO RECOVER IV STUDY." To guarantee you will not be enrolled at a participating hospital, you should wear this wristband during the 2023-2028 study duration.

WHERE CAN I LEARN MORE?

1-888-249-6558

Email: recover4@uw.edu

WWW.R4STUDY.COM/FAQS

RECOVER IV

RECOVER IV

Emergency care research study in patients with heart attack and heart shock

What is heart shock?

Heart shock happens when a heart attack is large enough that the heart cannot pump enough blood to the rest of the body. This is a medical emergency that requires immediate treatment.

How do doctors treat heart shock?

There are different strategies to treat heart shock. Some doctors use drugs to help maintain blood pressure and to encourage the heart to pump harder. Some doctors use devices to assist the heart to function better. One device that doctors may use is called a temporary heart pump. This device helps move blood from the heart to the rest of the body.

Despite existing treatments, about half of patients with heart shock die before leaving the hospital. The best strategy to improve survival from heart shock is unknown.

What is RECOVER IV?

RECOVER IV is a research study that will evaluate if using a temporary heart pump improves the heart's ability to recover from heart shock when combined with other standard treatments. RECOVER IV will be conducted at 40 hospitals across the United States between 2023–2028. Abiomed, Inc. is sponsoring and funding RECOVER IV.

This brochure provides details about this study in your community. You can learn more at **www.R4study.com/FAQs**