

Clinical Study Information

Empower BP is currently recruiting candidates who have symptomatic blood pressure instability following a chronic spinal cord injury (more than one year after injury).

Interested in participating or want to learn more?

Visit our website, or scan the QR code:

<https://onwd.com/empower-bp>



Contact the study team at Craig Hospital:

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www.clinicaltrials.gov
NCT07147296

Study Purpose

Following a spinal cord injury (SCI), **blood pressure (BP) can fluctuate** between inappropriately low and high values due to disruptions in the autonomic nervous system:

	Orthostatic Hypotension (OH) ¹	Autonomic Dysreflexia (AD) ²
Type	Low BP	High BP
Cause	Posture or changes in posture, such as moving from a reclined to an upright position or remaining seated upright	Stimuli below the level of a spinal cord injury, such as a full bladder or pain, which are no longer perceived after the injury
Symptoms	Dizziness, lightheadedness, blurred vision, and fatigue	Headaches and heart palpitations, goosebumps and sweating, as well as anxiety

The **Empower BP** global pivotal study evaluates the safety and effectiveness of the investigational implantable ARC[™] System* for treating **symptomatic blood pressure instability** in individuals with chronic SCI.



The study uses the investigational implantable ARC[™] System*, which delivers targeted, programmed stimulation of the spinal cord to address symptomatic blood pressure instability in individuals with SCI.

ARC[™] targets the **Hemodynamic Hotspot** in the thoracic spinal cord, a **key region for blood pressure regulation**.¹ By stimulating this area, it aims to alleviate symptoms of blood pressure instability after SCI.

While ARC[™] remains an investigational device and is only available as part of a clinical study, some preliminary benefits of participating in this research may include:

- Stable blood pressure
- Increased tolerance to position transfer
- Improved mental awareness
- Increased physical activity
- Greater engagement in rehabilitation and activities of daily living (ADLs)
- Improved quality of life

Main inclusion criteria:

- Be >1 year post-injury
- Be aged 18–75
- Have a traumatic, chronic spinal cord injury between levels C2–T6 (inclusive)
- Have been diagnosed with sustained hypotension
- Have no history of hypotension prior to injury
- Have an ASIA classification of A, B, C, or D

All clinical studies involve potential risks and discomforts that should be carefully considered. Additional information is available at www.onwd.com/empower-bp.

Main exclusion criteria:

- Have history of heart attack, severe heart rhythm disorder, or stroke in the past six months
- Have kidney or liver disease
- Be on a ventilator
- Have an active implanted medical device (e.g., baclofen pump or pacemaker)
- Be pregnant or breastfeeding
- Be unable to receive a spinal MRI

Please consult your study team or healthcare professional to understand the complete list of potential inclusion and exclusion criteria. Participant involvement spans 24–28 months, during which you will have a series of follow-up visits to assess how the therapy works for you.

1. Phillips, A.A., et al. "An implantable system to restore hemodynamic stability after spinal cord injury." *Nature Medicine*. 2025. 2. Soriano, J.E., et al. "A neuronal architecture underlying autonomic dysreflexia." *Nature*. 2025

*Caution: Investigational device. The safety and effectiveness of this therapy are currently being evaluated in clinical studies and are under review by the U.S. Food and Drug Administration (FDA). Limited by United States law to investigational use. ARC[™]®, ARC[™]® logo, ARC Therapy[™], ONWARD®, ONWARD® Medical logo, and O® logo are trademarks or registered trademarks of ONWARD Medical. Unauthorized use is strictly prohibited. © 2025 ONWARD Medical. All Rights Reserved. 2025042A

