

ARC-IM System to Manage Symptomatic Blood Pressure Instability Secondary to Chronic Spinal Cord Injury

NCT07147296

Status	RECRUITING
Phase	Not Applicable
Sponsor	ONWARD Medical, Inc.
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (15)

- Aged 18 years or above, and no older than 75 years at the time of enrollment.
 - Clinical evidence of Orthostatic Hypotension (blood pressure drop of 20mmHg systolic or 10mmHg diastolic) measured during Head Up Tilt Table assessment (HUTT, within 10 minutes) with current standard of care if any. 2 out of 3 tests must meet OH criteria.
 - Clinical evidence of sustained hypotension (average systolic Blood pressure \leq 110 mmHg) when measured each minute for 10 minutes while seated and in the absence of supportive compressive garments and medication.
 - Evidence of symptomatic hypotension as determined by a non-zero OHSA total score
 - A Spinal cord injury at the neurologic level between C2 and T6 inclusive.
- ... and 10 more (see full listing online)

Exclusion (21)

- Subject has an autoimmune etiology of spinal cord dysfunction/injury.
 - Subject has diseases and conditions that would increase the morbidity and mortality of the surgical procedures required by the study.
 - Subject has a history of physiologic hypotension prior to SCI
 - Subject has a history of unexpected blood pressure instability related to medications
 - Inability to withhold antiplatelet/anticoagulation agents perioperatively.
- ... and 16 more (see full listing online)

Locations (5 total)

Craig Hospital, Englewood, Colorado, United States
University of Miami, Miami, Florida, United States
UofL Health - Frazier Rehabilitation Institute, Louisville, Kentucky, United States
... and 2 more locations