Imperative Trial: A prospective, multi-center, open label and single arm clinical investigation to evaluate the safety and efficacy of using the Zoom Reperfusion System in thrombectomy procedures to treat acute ischemic stroke patients

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Protocol Synopsis

Trial Name	Imperative Trial
Sponsor	Imperative Care, Inc.
Trial Number	ICI-001
Title	A prospective, multi-center, open label and single arm clinical investigation to evaluate the safety and efficacy of using the Zoom Reperfusion System in thrombectomy procedures to treat acute ischemic stroke patients
Investigational or Trial Device	The Zoom Reperfusion System uses single lumen catheters that have been specifically designed to track through the tortuous anatomy of the neurovasculature and are intended to be used, in conjunction with a vacuum source, to remove thrombus in order to restore blood flow to the brain during an acute ischemic stroke. The Zoom Reperfusion System includes the commercially available Imperative Care 0.088" ID Catheters and the Zoom Reperfusion Catheters (0.035" to 0.071" ID Catheters), Zoom Aspiration Tubing, and Zoom Aspiration Pump (or equivalent vacuum pump). The Imperative Care 0.088" ID Catheters have FDA clearance for facilitating introduction of interventional devices into the neurovasculature and the Zoom Reperfusion Catheters, with the Zoom Aspiration Tubing and Zoom Aspiration Pump (or equivalent aspiration pump), have FDA clearance for direct aspiration of thrombus from the neurovasculature. Within this trial, the Imperative Care 0.088" ID Catheters will be used as the primary access device for all cases and direct aspiration where feasible. If a Zoom Reperfusion Catheter is used for direct aspiration, the Imperative Care 0.088" ID Catheter should be positioned as close to the occlusion as possible and aspiration applied as the Zoom Reperfusion Catheter is retracted into the lumen of the Imperative Care 0.088" ID Catheter.
Objectives	To assess the safety and efficacy of the Zoom Reperfusion System in subjects diagnosed with acute ischemic stroke and undergoing mechanical thrombectomy procedure.
Control Devices	N/A - This is a single arm study.

Indications for Use	The Zoom Reperfusion System, including the Zoom Aspiration Tubing and Zoom Aspiration Pump (or equivalent vacuum pump), are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous thrombolytic therapy or who fail thrombolytic therapy are candidates for treatment.
Clinical Trial/ Investigation Design	Prospective, Multicenter, Open label, Single arm study to assess safety and reperfusion success following thrombectomy within 8 hours of stroke onset
Subject Population	Acute ischemic stroke patients eligible for mechanical thrombectomy within 8 hours of symptom onset or time last seen normal and meeting all trial inclusion/exclusion criteria.
Number of Subjects	Up to 350 subjects will be enrolled to yield 262 evaluable subjects after excluding the post consent screen failures. Enrollment will stop when the target number of evaluable subjects or enrollment limit has been reached.
Number of Arms/Randomization	Single arm/No randomization
Number of Centers	Up to 30 sites (US)

Trial Endpoint(s)	Primary Efficacy Endpoint: The primary efficacy endpoint is reperfusion success, defined as achieving a mTICI score ≥ 2b in three or less passes of the Zoom Reperfusion System (primary modality) without using additional thrombectomy devices or rescue therapy. Secondary Efficacy Endpoints: • Time to achieve mTICI score ≥ 2b, defined as the time from groin puncture to physician assessment of mTICI score ≥ 2b • The mTICI 3 success rate, defined as the proportion of patients achieving mTICI score 3 flow • First pass success rate (mTICI score ≥ 2b), defined as the proportion of patients where the primary treatment was accomplished with the first pass • The mTICI 2c success rate, defined as the proportion of patients achieving mTICI score ≥ 2c flow • Modified Rankin Scale (mRS) ≤2 at 90 days using the primary treatment modality • Quality of Life Assessement, measured by Stroke Impact Scale (SIS) Questionnaire. Primary Safety Endpoint: • Symptomatic intracranial hemorrhage (sICH), as confirmed by imaging, at the 24-hour post-procedure visit Secondary Safety Endpoints: • 90-day all-cause mortality • Intracranial hemorrhage (ICH) as confirmed by imaging at the 24-hour post-procedure visit • Embolization in new territory (ENT) • All serious adverse device effects (SADEs) through 90 days post-procedure • All serious adverse events through 90 days
Follow-up	Subjects will be followed for 90 days post-procedure, combining office visits and phone contact

Inclusion Criteria	1. Age 18 and older 2. NIHSS >=6 3. The operator feels that the stroke can be treated with endovascular thrombectomy approaches and the interventionalist estimates that groin puncture can be achieved within 8 hours from time last seen well 4. Pre-event mRS scale 0-1 5. Large vessel occlusion of the intracranial internal carotid artery (ICA), middle cerebral artery (MCA)-M1 or M2 segments, basilar, or vertebral arteries as evidenced by MRA or CTA 6. For strokes in anterior circulation, ASPECTS >=6; For strokes in posterior circulation, pc-ASPECTS >=8 7. Non-contrast CT/CTA or MRI/MRA for trial eligibility performed or repeated at treating stroke center or outside medical facility within 2 hours of treatment initiation 8. If indicated per American Heart Association clinical guidelines, thrombolytic therapy should be administered as soon as possible 9. Consenting requirements met according to local IRB or Ethics Committee
Exclusion Criteria	1. Female known to be pregnant at time of admission 2. Patient has suffered a stroke in the past 3 months 3. Presence of an existing or pre-existing large territory infarction 4. Pre-existing neurological or psychiatric disease that would confound the neurological or functional evaluation, e.g., dementia with prescribed anti-cholinesterase inhibitor 5. Known history of severe contrast allergy or absolute contraindication to iodinated contrast 6. Clinical history, past imaging or clinical judgement suggest that the intracranial occlusion is chronic 7. Life expectancy of less than 6 months prior to stroke onset 8. Clinical symptoms suggestive of bilateral stroke or stroke in multiple territories 9. Subject participating in another clinical trial involving an investigational device or drug 10. Known cancer with metastases 11. Evidence of active systemic infection 12. Any known hemorrhagic or coagulation deficiency

Imaging Exclusion Criteria	13. Evidence of intracranial hemorrhage on CT/MRI 14. CTA or MRA evidence of carotid stenosis requiring treatment for intracranial access 15. Excessive vascular access tortuosity or target vessel size that will likely prevent endovascular access with the Imperative Care 0.088" ID Catheters 16. Intracranial stent implanted in the same vascular territory that would preclude the safe deployment/removal of the thrombectomy devices 17. Occlusions in multiple vascular territories (e.g., bilateral anterior circulation, or anterior circulation/vertebrobasilar system) as confirmed on CTA/MRA, or clinical evidence of bilateral strokes or strokes in multiple territories as determined by the treating physician 18. Significant mass effect with midline shift as confirmed on CT/MRI 19. Evidence of intracranial tumor (except small meningioma defined as ≤ 3cm and asymptomatic) as confirmed on CT/MRI 20. Angiographic evidence of pre-existing arterial injury, e.g., carotid dissection, complete cervical carotid occlusion, or vasculitis
Determination of Sample Size	The sample size for this trial was based on determining the number of subjects needed to demonstrate that the performance goals established for the primary safety and efficacy endpoints, as well as the first Secondary Safety endpoint, will be met with 90% probability of success or power.
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