Clinical Study to Evaluate the Safety and Effectiveness of Arcevo LSA

NCT07089576

Status	RECRUITING
Phase	Not Applicable
Sponsor	Artivion Inc.
Enrollment	132 participants

Key Eligibility Criteria

Inclusion (17)

- e18years of age or d80 years of age (male or female) at time of surgery
- Patient has one of the following indications for open surgery based on computed tomography angiography (CTA) completed within 90 days of informed consent:
- Acute, subacute, or chronic dissection that involves the aortic arch and the descending thoracic aorta, with or without involvement of the ascending aorta
- Aneurysm that involves the aortic arch and the descending thoracic aorta, with or without involvement of the ascending aorta
- Patient, or patient's legally authorized representative (LAR; in the secondary arm only), provides written informed consent prior to any study procedures

... and 12 more (see full listing online)

Exclusion (19)

- Patient is pregnant, or planning to become pregnant during the course of the study; individuals of child-bearing potential must agree to use acceptable methods of contraception during the study
- Patient has another medical condition (aside from the arch disease) that, in the opinion of the investigator, reduces the patient's life expectancy to \< 2 years
- Patient has an existing aortic stent graft device in the descending aorta that would interact with Arcevo™ LSA
- Patient has a medical, social, or psychological problem that, in the opinion of the investigator, could impede the patient's ability to return for follow-up
- Patient is unwilling or unable to comply with the follow-up schedule

... and 14 more (see full listing online)

Locations (10 total)

University of Southern California, Los Angeles, California, United States
Emory University School of Medicine, Atlanta, Georgia, United States
Northwestern University Feinberg School of Medicine, Chicago, Illinois, United States
... and 7 more locations