False Lumen Treatment for Prevention of Aortic Growth Using Shape Memory Polymer - First-in-Human Study

NCT06550986

Status	RECRUITING
Phase	Not Applicable
Sponsor	Shape Memory Medical, Inc.
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (3)

- e18years of age.
- A candidate for false lumen (FL) embolization with a type B dissection, and no prior primary entry tear/TL treatment, OR
- A candidate for FL embolization with a type B or type A dissection, in whom the primary entry tear/TL was treated in a previous procedure, and is now presenting with a FL requiring treatment.

Exclusion (24)

- An inability to provide informed consent.
- Enrolled in another clinical study other than a registry.
- Hyperacute or acute aortic dissection (\<15 days from symptom onset).
- Untreated or uncovered primary entry/reentry tear proximal to left subclavian artery (before FL treatment with the investigational product).
- Vascular disease, aortic rupture, and/or anatomy and/or dissection membrane condition that precludes the safe access and positioning of an introducer sheath and delivery (and expansion) of the investigational product into the FL.

... and 19 more (see full listing online)

Locations (2 total)

Auckland City Hospital, Auckland, New Zealand
Waikato Hospital, Hamilton, New Zealand