

Early Feasibility of 'Pivot Extend' for Tricuspid Regurgitation Treatment

NCT06877520

Status	RECRUITING
Phase	Not Applicable
Sponsor	Tau-MEDICAL Co., Ltd.
Enrollment	7 participants

Key Eligibility Criteria

Inclusion (7)

- Adults 18 years of age or older at the time of screening
- Those with symptoms despite medical therapy (OMT, diuretics/medications) for TR for at least 1 month at screening
- Those who meet the criteria of severe (3+) or worse on the TR grade classification table on echocardiography performed at the screening visit
- Those with clinical symptoms of New York Heart Association (NYHA) class 2 or worse
- Those deemed suitable for percutaneous valve intervention by a Heart Team that includes at least one cardiologist, one cardiac surgeon and one anesthesiologist.

... and 2 more (see full listing online)

Exclusion (25)

- Those with blood clots, emboli, masses, or growths in the vascular system of the heart or lungs on an echocardiogram and cardiac CT scan performed at the screening visit
- Those with uncorrected blood clotting disorders based on hemanalysis performed at the screening visit
- Those who are unable to use anticoagulant agents (NOAC ex.Xarelto)
- Those who have had major bleeding (not including minor bleeding, such as a nosebleed that can be hemostasized) treated with anticoagulants prior to participation in this clinical trial
- Those with severe anemia (hemoglobin f10g/dL) that requires hospitalization

... and 20 more (see full listing online)

Locations (3 total)

Israeli-Georgian Medical Research Clinic Healthycore, Tbilisi, K'alak'i T'bilisi, Georgia
Tbilisi Heart and Vascular Clinic, Tbilisi, K'alak'i T'bilisi, Georgia
Tbilisi Heart Center, Tbilisi, K'alak'i T'bilisi, Georgia