

Non-antithrombotic Therapy After Transcatheter Aortic Valve Implantation Trial

NCT06007222

Status	RECRUITING
Phase	Phase 4
Sponsor	OCEAN-SHD Study Group
Enrollment	400 participants

Key Eligibility Criteria

Inclusion (3)

- Patients who underwent transfemoral TAVI for aortic stenosis
- Patients aged 20 years or older at the time of informed consent
- Patients who have a thorough understanding of the subject of the study and who have agreed in writing to participate in the study

Exclusion (11)

- Those with perioperative complications at the time of TAVI (conversion to open heart surgery, coronary artery occlusion, annulus rupture, cardiac tamponade, vascular dissection, cerebral infarction/cerebral hemorrhage, new atrial fibrillation, new atrioventricular block)
 - Individuals requiring antiplatelet agents for reasons other than TAVI (history of myocardial infarction, history of PCI Percutaneous Coronary Intervention, history of EVT EndoVascular Treatment, history of cerebral infarction and transient ischaemic stroke, with significant coronary artery narrowing, with high-grade carotid artery narrowing, and others judged as requiring antiplatelet therapy by the chief researcher or a sub-investigator)
 - Patients requiring oral anticoagulants (patients with atrial fibrillation, history of pulmonary embolism or deep venous thrombosis, and other patients who are deemed to require anticoagulation therapy by the investigator or coinvestigator)
 - Patients with eGFR estimated Glomerular Filtration Rate ≤ 30 and patients on hemodialysis/peritoneal dialysis.
 - Patients with a history of valve replacement in the heart valves.
- ... and 6 more (see full listing online)

Locations (1 total)

Keio University Hospital, Shinjuku, Tokyo, Japan