A Clinical Evaluation of AMJ-401

NCT07373353

Status	RECRUITING
Phase	Not Applicable
Sponsor	Abbott Medical Devices
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (9)

- Subject must be at least 18 years of age.
- Subject or a legally authorized representative must be able to provide written Informed Consent prior to any study related procedure, per site requirements.
- Subject must have evidence of myocardial ischemia (e.g., stable angina, silent ischemia, unstable angina, acute myocardial infarction) suitable for elective PCI.
- Subject must be an acceptable candidate for coronary artery bypass graft (CABG) surgery.
- Subject must be able to take dual antiplatelet therapy (DAPT) for minimum of 12 months following the index procedure and anticoagulants prior/during the index procedure, and the subject has no known allergic reaction, hypersensitivity or contraindication to aspirin, clopidogrel, prasugrel, ticagrelor, ticlopidine or heparin.

... and 4 more (see full listing online)

Exclusion (33)

- Elective surgery planned within 12 months after the procedure that will require general anesthesia or discontinuing either aspirin or P2Y12 inhibitor.
- Subject has known hypersensitivity or contraindication to device material and its degradants (everolimus, PLLA, PDLLA, platinum, lactic acid, and lactide) that cannot be adequately pre-medicated.
- Subject has a known contrast sensitivity that cannot be adequately pre-medicated.
- Subject with known diagnosis of ST-elevation myocardial infarction (STEMI) within 72 hours of the index procedure.
- The subject is currently experiencing clinical symptoms consistent with new onset acute myocardial infarction (AMI), such as nitrate-unresponsive prolonged chest pain with ischemic ECG changes.

... and 28 more (see full listing online)

Locations (1 total)

Mitsui Memorial Hospital, Tokyo, Chiyoda-ku, Japan