TECTONIC CAD IVL IDE Study

NCT06885177

Status	RECRUITING
Phase	Not Applicable
Sponsor	Abbott Medical Devices
Enrollment	335 participants

Key Eligibility Criteria

Inclusion (17)

- Subject must be at least 18 years of age.
- Subject must sign and date a written informed consent form before any study-specific tests or procedures are performed.
- Subject is able and willing to comply with all protocol requirements.
- Subject has native coronary artery disease (including stable or unstable angina and silent ischemia) suitable for PCI.
- For subject with unstable ischemic heart disease, cardiac biomarker (troponin) must be less than or equal to the upper reference limit (URL) within 12 hours prior to the procedure.

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

Exclusion (35)

- Subject has other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator's opinion, could limit the subject's ability to participate in the clinical investigation or to comply with follow-up requirements of the clinical investigation results.
- Subject is a member of a vulnerable population including individuals with mental disability, persons in nursing homes, children, impoverished persons, persons in emergency situations, homeless persons, nomads, refugees, and those incapable of giving informed consent.
- Subject is participating in another research study involving an investigational agent (pharmaceutical, biologic, or medical device) that has not reached the Primary endpoint. For the purposes of this criterion, "participation" is defined as being registered in another trial.
- Pregnant or nursing subjects and those who plan pregnancy during the clinical investigation follow-up period. For subjects with childbearing potential, a urine or blood pregnancy test is required within 7 days prior to index procedure to verify that subject is not pregnant. Note: Investigators should instruct female patients of childbearing potential to use safe contraception for 12 months after the procedure (e.g., intrauterine devices, hormonal contraceptives: contraceptive pills, implants, transdermal patches, hormonal vaginal devices, injections with prolonged release). It is acceptable to include subjects having a sterilized regular partner.
- Subject unable to tolerate dual antiplatelet therapy (i.e., aspirin, and either clopidogrel, prasugrel, or ticagrelor) for at least 6 months.

... and 30 more (see full listing online)

Locations (41 total)

HonorHealth, Scottsdale, Arizona, United States
Arkansas Heart Hospital, Little Rock, Arkansas, United States
Kaiser Permanente - San Francisco, San Francisco, California, United States
... and 38 more locations