AGENT DCB STANCE: Safety and Effectiveness Study of AGENT Drug-Coated Balloon Compared to Standard of Care Percutaneous Coronary Intervention (PCI) Treatment for de Novo Coronary Lesions

NCT06959524

Status	RECRUITING
Phase	Not Applicable
Sponsor	Boston Scientific Corporation
Enrollment	1,616 participants

Key Eligibility Criteria

Inclusion (9)

- Subject must be at least 18 years of age.
- Subject (or legal guardian) understands the trial requirements and the treatment procedures and provides written informed consent before any trial-specific tests or procedures are performed.
- Subject is eligible for percutaneous coronary intervention (PCI).
- Subject is willing to comply with all protocol-required follow-up evaluation.
- Women of child-bearing potential must agree to use a reliable method of contraception from the time of screening through 12 months after the index procedure.

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

Exclusion (25)

- Subject has other serious medical illness (e.g. cancer, congestive heart failure) that may reduce life expectancy to less than 12 months.
- Subject has current problems with substance abuse (e.g. alcohol, cocaine, heroin, etc.).
- Subject has planned procedure that may cause non-compliance with the protocol or confound data interpretation.
- Subject is participating in another investigational drug or device clinical study that has not reached its primary endpoint.
- Subject intends to participate in another investigational drug or device clinical study within 12 months after the index procedure.

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

Locations (41 total)

Scripps Memorial Hospital, La Jolla, California, United States
USC Medical Center, Los Angeles, California, United States
Cedars - Sinai Medical Center, Los Angeles, California, United States
... and 38 more locations