



Prairie

EDUCATION & RESEARCH COOPERATIVE

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TAXUS PERSEUS - Workhorse

Trial Sponsor: Boston Scientific

Principal Investigator: Gregory Mishkel, MD

Trial Name: A Prospective Evaluation in a Randomized Trial of the Safety and Efficacy of the Use of the TAXUS Element Paclitaxel-Eluting Coronary Stent System for the Treatment of De Novo Coronary Artery Lesions

Purpose: The purpose of the TAXUS PERSEUS Workhorse trial is to evaluate the safety and efficacy of the next-generation Boston Scientific TAXUS paclitaxel-eluting coronary stent system (TAXUS® Element™) for the treatment of de novo atherosclerotic lesions of up to 28mm in length in native coronary arteries of 2.75mm to 4.0mm diameter.

Details: This is a prospective, 3:1 randomization, multi-center trial to assess the TAXUS® Element™ Paclitaxel-Eluting Coronary Stent System for the treatment of de novo atherosclerotic lesions of up to 28mm in length in native coronary arteries $\geq 2.75\text{mm}$ and $\leq 4.0\text{mm}$ in diameter, compared to a control group of TAXUS Express2 stents.

One thousand two hundred sixty-four (1264) subjects will be treated with either the TAXUS® Element™ stent or the TAXUS® Express2™ stent at a maximum of 100 clinical sites. Randomization to treatment group will be unbalanced 3:1 towards the test group to gain maximum clinical experience with the new TAXUS® Element™ platform. Follow-up at 30 days, 9 months, and 12 months will be completed in all subjects enrolled in the study. Angiographic follow-up at 9 months will be completed in a subset of three hundred thirty (330) subjects enrolled in the study. Subjects will be randomly allocated to the angiographic subset at participating sites through the Interactive Voice Response System (IVRS).

Eligible subjects will have annual follow-up until 5 years post-index procedure.

Phase: Phase III

Study Type: Interventional

Study Design: Treatment, Randomized, Single Blind, Active Control, Parallel Assignment, Safety/Efficacy Study

Study Arms: 2



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Expected Enrollment: 1264

Primary Outcome Measures:

- Target Lesion Failure (TLF) rate at 12 months post-index procedure [Time Frame: 12 months post-index procedure]

Secondary Outcome Measures:

- In-segment percent diameter stenosis at 9 months post-index procedure [Time Frame: 9 months post-index procedure]

Eligibility:

Ages Eligible for Study: 18 years – 80 years

Genders Eligible for Study: Both

Inclusion Criteria:

Key Clinical Inclusion Criteria:

- Subject is ≥ 18 years old and ≤ 80 years old
- Eligible for percutaneous coronary intervention (PCI)
- Documented stable angina pectoris or unstable angina pectoris with documented ischemia, or documented silent ischemia

Key Angiographic Inclusion Criteria:

•Target Lesion

- Reference vessel diameter (RVD) ≥ 2.75 mm to ≤ 4.0 mm
- Cumulative target lesion length ≤ 28 mm

Key Clinical Exclusion Criteria:

- Contraindication to ASA, or to both clopidogrel and ticlopidine
- Myocardial infarction (MI) within 72 hours prior to index procedure