Evaluation of the Safety & Effectiveness of the PROMUS Element Everolimus-Eluting Coronary Stent System in patients with new or untreated atherosclerotic coronary artery lesions

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Status	RECRUITING
Sponsor	Boston Scientific Pty Ltd
Enrollment	102 participants

Plain Language Summary

This study is testing a heart stent — a small mesh tube placed inside a narrowed heart artery — called the PROMUS Element Everolimus-Eluting Coronary Stent, in patients with longer blockages (24 to 34 mm) in their heart arteries. Heart artery disease (coronary artery disease) can cause chest pain and heart attacks. A stent is placed during a procedure called PCI (percutaneous coronary intervention) to hold the artery open. This drug-eluting stent releases a medication called everolimus to prevent the artery from re-narrowing. The PLATINUM LL trial will follow patients for 12 months to assess safety and effectiveness.

You may be eligible if:
- You are 18 years of age or older
- You have documented stable or unstable angina or silent ischaemia
- You have a new (untreated) narrowing in a native coronary artery that is 24–34 mm long
- Your heart pumping function is above 30%
- You would be a candidate for bypass surgery if needed

You may NOT be eligible if:
- You have had a heart attack within 72 hours before the procedure with elevated cardiac enzymes
- The target artery was treated with any intervention in the past 12 months
- You are on chronic anticoagulation therapy
- You are pregnant, nursing, or planning pregnancy within 12 months

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (9)

- Patient is eligible for percutaneous coronary intervention (PCI)
- Patient has documented stable angina
- pectoris, or documented silent ischaemia, or
- unstable angina pectoris
- Patient is acceptable candidate for Coronary Artery Bypass Graft (CABG)

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

Exclusion (6)

- Clinical symptoms or Electrocardiogram (ECG) changes consistent with Myocardial Infarction (MI)
- Patient has known diagnosis of recent MI
- (within 72 hours prior to index procedure) and has elevated enzymes at time of index procedure
- Target vessel or side branch treated with any type of PCI within 12 months prior to index procedure
- Patient is receiving chronic anticoagulation therapy for indications other than acute coronary syndrome

... and 1 more (see full listing online)

Locations (3 total)

New Zealand
Japan
United States of America