A Continuation in the Clinical Evaluation of the Abbott Vascular Everolimus-Eluting Bioresorbable Vascular Scaffold in the Treatment of Subjects With de Novo Native Coronary Artery Lesions

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Status	RECRUITING
Sponsor	Abbott Vascular
Enrollment	1,000 participants

Plain Language Summary

This study is continuing to evaluate a new type of biodegradable (dissolving) heart stent called the Bioresorbable Vascular Scaffold (BVS). Unlike traditional metal stents that stay in the artery permanently, this scaffold is designed to support the artery while it heals and then gradually dissolve away. The study is assessing how safe and effective this device is in treating blockages in coronary arteries.

You may be eligible if:
- You are 18 years of age or older
- You have one or two narrowed areas in separate coronary arteries that need treatment
- The blockage is at least 50% narrowed but not completely blocked
- The blocked artery is large enough (reference vessel over a certain diameter)

You may NOT be eligible if:
- Your blockage is in a bypass graft (artificial artery)
- The blocked artery is completely blocked with no blood flow at all before the wire is passed
- There is a blood clot visible in the target artery
- Your blockage involves a branching point with a significant side vessel
- You have previously had radiation treatment inside the heart arteries

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

Key Eligibility Criteria

Inclusion (5)

- Up to two de novo lesions can be treated, each located in a separate native epicardial vessel.
- Target lesion(s) must measure <= 28 mm in length by Qualitative Coronary Angiography (QCA), or by visual estimation if on line QCA is not available.
- Target lesion(s) must be in a major artery or branch with a visually estimated stenosis of >= 50% and < 100% with a Thrombolysis in Myocardial Infarction (TIMI) flow of >= 1.
- Percutaneous interventions for lesions in a non-target vessel are allowed if done >= 30 days prior to or if planned to be done > 6 months after the index procedure.
- Percutaneous intervention for lesions in the target vessel are allowed if done > 6 months prior to or if planned to be done 6 months after the index procedure.

Exclusion (6)

- Lesion(s) located within an arterial or saphenous vein graft or distal to a diseased (defined as vessel irregularity per angiogram and > 20% stenosed lesion by visual estimation) arterial or saphenous vein graft.

• Lesion(s) involving a bifurcation with side branch vessel >= 2 mm in diameter, ostial lesion > 40% stenosed by visual estimation or side branch requiring predilatation.

• Total occlusion (TIMI flow 0), prior to wire passing.

• Target vessel(s) contains visible thrombus.

• Another clinically significant lesion is located in the same epicardial vessel (including side branch) as the target lesion(s).

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

Locations (9 total)

Belgium
Brazil
France
... and 6 more locations