

Abbott expanding study of its popular Xience stent

August 13 2009, By LINDA A. JOHNSON , AP Business Writer

(AP) -- Abbott Laboratories Inc. is expanding a study of its top-selling heart stent by more than 2,000 patients, who may also be put in a second, landmark stent study meant to find the best way to prevent potentially fatal blood clots.

The bigger study aims to determine the optimum time people should take blood-thinning medicines after they undergo a common procedure called angioplasty to clear out a blocked artery and implant a stent, a metal-mesh scaffold that props open a blood vessel. That study, begun late last year, includes more than 25,000 patients and academic researchers, federal regulators and eight major prescription drug and medical device makers.

Abbott, of North Chicago, Ill., said Thursday it is expanding a study of its already-approved Xience V stent. Those patients will be followed for five years to see how many develop a blood clot near the site of the stent and will be eligible to also enroll in the larger study.

That study was requested by the Food and Drug Administration to help doctors figure out the best treatment for their patients. It was designed and is being overseen by the Hartford Clinical Research Institute.

Because of its huge size and cost, it involves and is partly supported by the four big U.S. stent makers - Johnson & Johnson, Boston Scientific Corp., Abbott and Medtronic Inc. - plus four large drugmakers that sell anticlotting medicines - Bristol-Myers Squibb Co., Sanofi Aventis SA,

Eli Lilly & Co. and Daiichi Sankyo.

Some patients will get bare-metal stents, but most will get newer ones coated with a drug to prevent re-clogging of the artery around the stent. Everyone will get at least 81 milligrams of aspirin a day and an anticlotting drug. After a year, those who haven't had complications will be split in two groups, with one continuing on the blood-thinning therapy for 18 months and the rest stopping it.

About 800,000 to 1 million American patients a year have one or more stents implanted after angioplasty. Less than 1 percent have a clot form near the stent, according to FDA officials, but that still leads to many strokes, heart attacks and deaths.

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Citation: Abbott expanding study of its popular Xience stent (2009, August 13) retrieved 10 April 2024 from <https://medicalxpress.com/news/2009-08-abbott-popular-xience-stent.html>

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