Dual Antiplatelet Therapy (DAPT) Study

Research Areas

Tool Development

Clinical Trial

At a Glance

- Status: Active Consortium
- Year Launched: 2009
- Initiating Organization: Harvard Clinical Research Institute
- Initiator Type: Academia
- Location: North America

Abstract

The Dual Antiplatelet (DAPT) Study was an independent, large-scale study in size and scope intended to determine the appropriate duration for dual antiplatelet therapy (the combination of aspirin and a second anti-clotting medication to reduce the risk of blood clots) to protect patients from stent thrombosis and major adverse cardiovascular and cerebrovascular events (MACCE) following the implantation of drug-eluting coronary stents.

Mission

The DAPT Study was an international initiative developed by a group of eight manufacturers (four major stent manufacturers and four manufacturers of antiplatelet medications) who joined together to address a U.S. Food and Drug Administration request for this postmarket study. The Harvard Clinical Research Institute (HCRI) was responsible for the scientific conduct and independent analysis of the overall study.
**Consortium History**

Nov. 16, 2014: Final Results from the DAPT Study were released at the American Heart Association Scientific Sessions.

**Structure & Governance**

The Executive, Advisory, and Manufacturers Operations Committees provided relevant expertise and guidance to HCRI and met independently throughout the DAPT Study. The size and scope of the study required a wide range of scientific, clinical, and ethical expertise organized through the collaborative structure of the following committees.

**Executive Committee:** The Executive Committee was responsible for the ongoing scientific management of the study. Committee members and other international physicians were key scientific advisors in the study design. In addition to the principal investigators, Donald Cutlip, M.D., Beth Israel Deaconess Medical Center and Harvard Medical School; Philippe Gabriel Steg of Centre Hospitalier Bichat-Claude Bernard and Université Paris VII; and Sharon-Lise Normand, Ph.D., Harvard School of Public Health and Harvard Medical School, served on the Executive Committee.

**Advisory Committee:** The Advisory Committee provided guidance to HCRI and the Executive Committee on matters related to study progress and conduct as well as the scientific issues that arose during the course of the study. The committee members were experienced physicians and clinical trial managers from the global cardiology community. The chairman was Eugene Braunwald, M.D., Brigham and Women’s Hospital and Harvard Medical School.

**Manufacturers Operations Committee:** This committee consisted of manufacturers supporting the study who shared expertise specific to their products and maintained oversight of funding.

**Data Monitoring Committee:** An independent Data Monitoring Committee (DMC) monitored patient safety throughout the study. The DMC consisted of physicians from the fields of cardiology and interventional cardiology and at least one biostatistician, who were not directly involved in the conduct of the study. The DMC reviewed the study enrollment and subject safety (including reported serious adverse events) on a regular basis. The chairman was Robert Bonow, M.D., Northwestern Memorial Hospital.
Intellectual Property

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Impact/Accomplishment

Final study results were released in November 2014. Data demonstrated that continuation of dual antiplatelet therapy beyond one year had a significant beneficial effect of reducing stent thrombosis and preventing heart attack in other vessels compared with aspirin alone. Although longer-term dual antiplatelet therapy expectedly increased bleeding, severe and/or fatal bleeding was uncommon and not different between study groups. The study investigators believe that the overall benefits of continuing dual antiplatelet therapy to 30 months after coronary stenting outweigh the bleeding risks and that these results warrant a shift in clinical practice toward longer-duration treatment in most patients.

Links/Social Media Feed

Homepage  
http://www.daptstudy.org/index.html

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