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The Role of the Data Safety Monitoring Board: Why Was the Avastin® Phase III Clinical Trial Stopped?

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In early February 2006, Genentech Inc. issued a joint press release with Roche Holding Corporation explaining that their phase III early-stage colon cancer trial of Avastin® (bevacizumab, Genentech Inc., South San Francisco, CA) would be stopped after the deaths of four patients. This announcement was the result of preliminary review of the data by the Data Safety Monitoring Board (DSMB) that was formed to monitor the study. What is the DSMB? What criteria does it use to determine whether a study should be stopped early? The purpose of this article is to (a) explain the role of the DSMB, (b) give an overview of the Avastin Adjuvant (AVANT) study, and (c) provide information and resources about clinical trials for practicing RNs in oncology.

Definition

According to Kaufmann and Schooler (2004), the DSMB is defined as "an independent committee whose membership includes, at minimum, a statistician and a clinical expert in that area being studied. Members may also include bioethicists or other clinicians knowledgeable about the trial's subject matter. The National Institutes of Health requires DSMB review of all phase III clinical trials. A DSMB might also review phase I or II trials that are blinded, take place at multiple locations, or employ particularly high-risk interventions or vulnerable populations."

The purpose of the DSMB is to provide interim data analysis for efficiency and safety during the execution of the study. Phase III clinical trials are conducted to compare new agents or interventions (or new use of a currently approved treatments) with a current standard (National Cancer Institute, 2006).

Background on the Trial

In 2004, Avastin was approved for use by the U.S. Food and Drug Administration as a first-line chemotherapeutic agent for metastatic colorectal cancer in conjunction with 5-fluorouracil (5-FU). Avastin is a therapeutic antibody that inhibits the vascular endothelial growth factor, which has a significant role in angiogenesis (Genentech Inc., n.d.). Avastin was not approved for use without chemotherapy and is initially a 90-minute infusion given once every 14 days at a dosage of 5 mg/kg for the treatment of metastatic solid tumors as long as clinicians recommend treatment (Genentech Inc., 2005).

The AVANT trial was initiated in December 2004 and was conducted by Genentech in partnership with Roche. The goal of the trial was to enroll 3,450 patients (using multiple sites) to three different treatment arms. Patients enrolled in arm one (the control arm) received oxaliplatin, 5-FU, and leucovorin (FOLFOX). Patients enrolled in arm two (FOLFOX plus Avastin) received the control arm medications in addition to Avastin. Patients enrolled in arm three received

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