

Cancer treatments in phase 3 trials successful up to half of the time

March 24 2008

About one-fourth to one-half of new cancer treatments that reach assessment in phase 3 randomized clinical trials are eventually proven successful, according to a report in the March 24 issue of *Archives of Internal Medicine*, one of the JAMA/Archives journals.

Cancer remains the second leading cause of death in the United States, but continuous improvements have been made in survival and other outcomes, according to background information in the article.

“To a large extent, this has occurred through the introduction of new treatments tested in clinical trials, with randomized controlled trials (RCTs) widely considered to be the most reliable method of assessing differences between the effects of health care interventions,” the authors write. “Cancer is the only disease for which the National Institutes of Health has consistently funded a cooperative clinical trial infrastructure. Despite this investment, little is known about the proportion of clinical trials that have led to the discovery of successful new treatments.”

Benjamin Djulbegovic, M.D., Ph.D., of the H. Lee Moffitt Cancer Center and Research Institute at the University of South Florida, Tampa, and colleagues extracted data from all completed phase 3 randomized clinical trials conducted by the National Cancer Institute cooperative groups since their inception in 1955. A total of 624 trials involving 216,451 patients were analyzed.

Overall, 30 percent of the trials had statistically significant results; in 80

percent of those cases, new treatments were superior to established protocols. The original researchers reported that the risk-benefit ratio favored new treatments in 41 percent of comparisons, while standard treatments were favored in 59 percent of comparisons.

“The real effects of new treatments compared with standard treatments in terms of patient outcomes such as survival is best measured by quantitative pooling of data,” the authors write. “When done this way, new treatments are, on average, found to be slightly superior to standard treatments, with a 5 percent relative reduction in the death rate. This, of course, should not be understood as the average effects of new discoveries being equally spread among all patients.” In 15 percent of the trials, breakthrough therapies were discovered; in 2 percent of the cases, these reduced the death rate by more than 50 percent.

Source: JAMA and Archives Journals

Citation: Cancer treatments in phase 3 trials successful up to half of the time (2008, March 24) retrieved 1 May 2024 from <https://medicalxpress.com/news/2008-03-cancer-treatments-phase-trials-successful.html>

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