

Discontinuation of randomized clinical trials common

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Approximately 25 percent of about 1,000 randomized clinical trials initiated between 2000 and 2003 were discontinued, with the most common reason cited being poor recruitment of volunteers; and less than half of these trials reported the discontinuation to a research ethics committee, or were ever published, according to a study in the March 12 issue of *JAMA*.

Conducting high-quality <u>randomized clinical trials</u> (RCTs) is challenging and resource-demanding. Trials are often not conducted as planned or are prematurely discontinued, which poses <u>ethical concerns</u>, particularly if results remain unreported, and may represent a considerable waste of scarce research resources. Currently, little is known about the characteristics and publication history of discontinued <u>trials</u>, according to background information in the article.

Benjamin Kasenda, M.D., of University Hospital Basel, Switzerland, and colleagues examined characteristics of 1,017 trials approved by 6 research <u>ethics</u> committees in Switzerland, Germany, and Canada between 2000 and 2003. Last follow-up of these RCTs was April 27, 2013.

Among the findings of the researchers:

- Overall, 253 RCTs (24.9 percent) were discontinued;
- Only 38 percent of discontinuations were reported to ethics committees;



- RCTs were most frequently discontinued because of poor recruitment (9.9 percent), followed by administrative reasons (3.8 percent) and futility (3.3 percent);
- Although discontinuation was common for RCTs involving patients (28 percent), it was rare for RCTs involving healthy volunteers (3 percent);
- Discontinued trials were more likely than completed trials to remain unpublished, as were those with industry sponsorship;
- Trials with investigator sponsorship (vs industry sponsorship) were at higher risk of discontinuation due to poor recruitment.

"Greater efforts are needed to make certain that trial discontinuation is reported to research ethics committees and that results of discontinued trials are published," the authors conclude.

More information: <u>DOI: 10.1001/jama.2014.1361</u>

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