Stopping clinical trials early often exaggerates treatment effects

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An international study of nearly 100 clinical trials that were stopped early due to positive treatment effects has found that many of those effects were exaggerated. The authors of the study -- published in the current issue of the *Journal of the American Medical Association* -- recommend that researchers resist pressures to end clinical trials early and continue trials for longer periods before even considering premature termination.

"Our research shows that in most cases early stopping of clinical trials resulted in misleading estimates of treatment effects. These misleading estimates are likely to result in misguided decisions about the trade-off between risks and benefits of a therapy," says Victor Montori, M.D., Mayo Clinic endocrinologist and corresponding author of the study. "On average, treatments with no effect would show a reduction in relative risk of almost 30 percent in stopped early trials. Treatments with a true relative risk reduction of 20 percent would show a reduction of over 40 percent."

The clinical trials that Dr. Montori and colleagues studied were ended early because of a convincing -- and usually large -- apparent difference between an experimental treatment and an existing standard therapy. The studies were ended so participants taking a placebo or less effective medications could also take the studied drug. It usually also allows physicians to prescribe the therapy sooner because it will reach the market earlier. Dr. Montori says almost everyone involved benefits from a trial ending early

-- doctors, researchers, funding sources,
pharmaceutical firms, scientific journals, even reporters -- everyone except the patient, who may end up receiving a therapy on the basis of misleading information about its benefits.

The researchers examined 63 medical questions regarding 91 truncated trials and compared them to 424 comparable trials that were not stopped early. Results showed that the studies that were stopped -- especially smaller trials of a few hundred participants -- had exaggerated or misleading treatment effects. Those misleading findings are often compounded downstream because researchers are less likely to return to the topic after what is perceived as a significant successful finding.

The authors recommend that researchers use restraint and truncate clinical trials only near the end of a study and then only with "a very good reason." Otherwise, says Dr. Montori, patients and physicians will be making treatment choices based on inaccurate information, or worse, opting for one treatment when another may be more appropriate.

Provided by Mayo Clinic