The Medical Letter®

On Drugs and Therapeutics

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IN BRIEF

Non-Inferiority Trials

Several Medical Letter readers have asked about the meaning of non-inferiority trials. A non-inferiority trial is a comparison with an active control to determine whether the difference in response between the new drug and the active control is small enough (less than some pre-specified margin) to demonstrate that the new treatment is not less effective (or is only slightly less effective) than the control in achieving the primary outcome.[1,2] Non-inferiority trials are appropriate when a proven effective treatment already exists and assigning some patients to a placebo group would be unethical because the treatment is life-saving or prevents irreversible injury.[3] The FDA recently issued guidelines on how to interpret a non-inferiority trial, how to choose a non-inferiority margin and how to analyze the results.[4]

1. Guidance for industry non-inferiority clinical trials. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM202140.pdf. Accessed December 17, 2010.
2. ICH Harmonised Tripartite Guideline. Choice of control group and related issues in clinical trials E10. http://private.ich.org/LOB/media/MEDIA486.pdf. Accessed December 17, 2010.
3. R Temple and SS Ellenberg. Placebo-controlled trials and active-control trials in the evaluation of new treatments. Part 1: ethical and scientific issues. Ann Intern Med 2000; 133:464.
4. FDA issues first draft guidance on noninferiority trial. http://www.fdanews.com/newsletter/article?articleId=124913&issueId=13475. Accessed December 17, 2010.