Abstract 1

General Information

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Abstract Information

Abstract Title : ClinicalTrials.gov registered data and results reporting agreement
Abstract : Background: Clinical trial registration and reporting in the context of legislative and organizational initiatives to encourage transparent clinical trial data reporting prevent overestimation of drug effectiveness and safety, and maintenance of public trust in clinical trials. Methods: Observational study of a cohort of ClinicalTrials.gov registered FDAAA-covered RCTs between 2009 and 2012 and data from corresponding publications. We determined: 1) completeness, clarity, and changes in 9 World Health Organization (WHO) Minimum Data Set registration items for protocols in ClinicalTrials.gov; 2) results data from initial to last registration for completed randomized controlled trials (RCTs); and 3) possible differences between the latest registered protocol data and results and published journal article. Results: Among 81 eligible trials, most were industry-funded, with a drug intervention in parallel assignment. Secondary outcomes at initial and last registration were omitted for 17% and 19.7% of RCTs, respectively. RCT registration changes mostly involved scientific title
Inclusion criteria omission was most common (88%) in publications. Inferential statistical methods for primary and secondary outcomes matched between registry and publication for 53.4% and 28.6% of RCTs, respectively. Serious and other adverse events that were absent for 23.8% and 4.8% of RCTs, respectively, were published as non-occurring. Conclusions: Discrepancies remain relatively high between registered and published outcomes, particularly regarding registered omissions in publications and concomitant reporting, nature of statistical method used, and reporting of adverse events. This seriously undermines transparency of clinical trials and needs immediate attention of all stakeholders in health research.