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Completeness and publication of the registered safety clinical studies involving children

We examined completeness and publication of the registered in clinicaltrials.gov studies involving children and identified 29,475 records in August 2012 including 9,080 studies with clear indication of testing safety in study aims or outcome measurements (thereafter “safety studies”). Safety studies constituted 55% of all studies of biologics, 35% of medical device studies, 33% of procedure studies, 31% of radiation studies, and 50% of drug studies. Study results were posted in clinicaltrials.gov for 5% of all studies or 9% for safety studies (Odds ratio (OR) of examining safety 2.99 for the studies with posted results vs. other studies, 95%CI 2.68 to 3.33). Completion rate was 36% for safety studies vs. 33% for overall studies (OR of examining safety 1.12 for completed studies vs. initiated but non completed studies, 95%CI 1.22 to 1.17). The studies enrolling exclusively children (OR 1.25 95%CI 1.19 to 1.32), testing drugs (OR 2.53 95%CI 2.4 to 2.67) or employing interventional design (OR 85 95%CI 66 to 108) examined safety more often. Industry sponsored studies examined safety more often than the studies sponsored exclusively by non for profit organizations (OR 2.8 95%CI 2.7 to 2.9). Our search in Medline for registered studies (clinicaltrials.gov[si]) identified 3,735 published journal articles of children (13% of all registered) and 1,267 published journal articles indexed as safety studies (14% of all registered safety studies or 22% of registered drug safety studies). Regulatory agencies should revise clinical research policy and mandate registration and posting of the results in clinicaltrials.gov from all studies involving children.

Biography

Tatyana Shamliyan has completed her M.D. in Russian Federation in 1984 and her Master in Science in Clinical Research from the University of Minnesota in 2005. She is a senior research associate in Minnesota Evidence Based Practice Center in the School of Public Health, University of Minnesota. She has published more than 50 papers in reputed journals and in the Agency of Healthcare Research and Quality evidence reports.

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