

The Ecosystem of Food Allergy Clinical Trials: A Systematic Review

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Abstract : Background: Science is not generally self-correcting; many clinical studies end with the same conclusion "more research is needed." This study hypothesizes that first, we need a better appraisal of the available (and unavailable) evidence instead of creating more of the same false inquiries. Methods: Systematic review of ClinicalTrials.gov study records using the following Boolean operators: (food OR nut OR milk OR egg OR shellfish OR wheat OR peanuts) AND (allergy OR allergies OR hypersensitivity OR hypersensitivities). Variables included the status of the study (e.g., active and completed), availability of results, sponsor type, sample size, among others. To determine the rates of non-publication in journals indexed by PubMed, an advanced search query using the specific Number of Clinical Trials (e.g., NCT000001 OR NCT000002 OR...) was performed. As a prophylactic measure to prevent P-hacking, data analyses only included descriptive statistics and not inferential approaches. Results: A total of 2092 study records matched the search query described above (date: September 13, 2019). Most studies were interventional (n = 1770; 84.6%) and the remainder observational (n = 322; 15.4%). Universities, hospitals, and research centers sponsored over half of these investigations (n = 1208; 57.7%), 308 studies (14.7%) were industry-funded, and 147 received NIH grants; the remaining studies got mixed sponsorship. Regarding completed studies (n = 1156; 55.2%), 248 (21.5%) have results available at the registry site, and 417 (36.1%) matched NCT numbers of journal papers indexed by PubMed. Conclusions: The internal and external validity of human research is critical for the appraisal of medical evidence. It is imperative to analyze the entire dataset of clinical studies, preferably at a patient-level anonymized raw data, before rushing to conclusions with insufficient and inadequate information. Publication bias and non-registration of clinical trials limit the evaluation of the evidence concerning therapeutic interventions for food allergy, such as oral and sublingual immunotherapy, as well as any other medical condition. Over half of the food allergy human research remains unpublished.

Keywords : allergy, clinical trials, immunology, systematic reviews

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