

Clinical trials should focus on quality: an investigation into the registration of clinical trials of COVID-19

Xinqi Teng¹, Tingting Qi¹, Guohua Li¹, Jiaojiao Wang¹, Qiang Qu¹, Yali Wu¹, Qiong Lu¹, and Jian Qu¹

¹Affiliation not available

September 8, 2020

Abstract

Background: The coronavirus disease 2019 (COVID-19) is threatening the lives and health of people all over the world since its outbreak in Wuhan, Hubei province, China. Up to now, thousands of clinical trials have been registered, but there are still no effective and specific drugs for COVID-19 treatment. Large randomized controlled clinical trials face many challenges and the quality of COVID-19 clinical trials is also worrying. **Methods:** We searched all the COVID-19 clinical trials registered on the Chinese Clinical Trials Registry and ClinicalTrials.gov on June 29, 2020. Then we extracted the basic information of these COVID-19 clinical trials and analyzed the current dilemma of clinical trials of COVID-19. **Results:** A total of 3021 studies were retrieved, including 665 trials from the Chinese Clinical Trial Registry and 2356 trials from ClinicalTrials.gov. Among these clinical trials, 293 and 1314 intervention studies were registered in the Chinese Clinical Trial Registry and ClinicalTrials.gov, respectively. Up to now, only 4.48% of these intervention trials have completed their recruitment, and there were still 11.60% of studies registered in the Chinese Clinical Trials Registry have not yet been approved by the ethics committee. Phase II and phase III studies that could prove the safety and effectiveness of drugs accounted for 42.25%. The median and interquartile range (IQR) of sample size was 100 (60, 200) and 384 (50, 120) in the Chinese Clinical Trial Registry and ClinicalTrials.gov, respectively. The number of randomized controlled trials (RCTs) were rare, and 50.71% of these studies were open-label. **Conclusions:** The quality of COVID-19 clinical trials that have been registered was low, and no reliable results have been published due to the design deficiency. Well-designed and cooperative trials are urgently needed to defeat the COVID-19 epidemic.

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