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Changing trends of clinical trials in India

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Introduction: India is fast emerging as one of global hubs for conducting clinical trials. Even then, it is estimated that out of 1,18,804 clinical trials in 178 countries, less than 2,000 (<2%) are being done in India compared to 9,352 (8%) in neighboring China (WHO). Number of deaths resulting from clinical trials has increased to an unendurable figure of 2,868 during the period 2005-2012. Till April 2013, only 12 clinical trials have been approved by the authority as compared to almost a three digit figure in last year. This was a rationale to analyze the current trends of trials in India.

Objective: To review number of clinical trials in India from 2011 to 2016 and study designs and to note the number of serious adverse events and deaths due to clinical trials.

Methods: Data was collected and categorized from the clinical trial registry India-forum. In order to review the recent statistics and trend, only active trials that open to recruitment were included. Negative impact of trials on Indian trial participants (death/adverse events), data was obtained from official web of health and family welfare department.

Results: Our observational study shows there is steady decline in number of global clinical trials in India, from 56 to merely 19 in 2016. Majority were active controlled trials (61) and multiple arm trials than placebo based trials (7). SAE related to the trials were confirmed in 2209 cases by Drug Controller General of India including 1335 deaths.

Conclusion: Because of time-consuming government approvals and rising allegations of unethical tests further hindering possibilities of gathering a large sample size of people. Dr. Singh, Drug Controller General of India (DCGI), gave relaxed norms will help India register its presence in the international market as it will give Indian scientists and doctors the much needed liberty. With relaxed norms we will give more research opportunities to scientists in India without compromising ethics.

Biography

Karthikeyan Swaminathan is currently pursuing MBBS from Saveetha Medical College, SIMATS. His area of research revolves around clinical trials, carried out under the mentorship of Dr. V Krishnan, Department of Pharmacology, SIMATS in India.

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