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Research Article

An analysis of clinical trials registered with CTRI in India from 2007 to 2015

Vihang S. Chawan, Sagar V. Badwane*, Kalpesh V. Gawand, Maheshi U. Chhaya

Department of Pharmacology, Topiwala National Medical College & B. Y. L. Nair Charitable Hospital, Mumbai Central, Mumbai, Maharashtra, India

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***Correspondence:**
Dr. Sagar V. Badwane,
E-mail: dr.sagarbadwane@gmail.com

ABSTRACT

Background: Clinical trials are gold standard in the field of evidence based medicine. Registration of clinical trials facilitates the dissemination of information among clinicians, researchers and patients. Earlier, researchers were interested only in publishing positive results of their study. The negative results were never published resulting in bias in reporting the results of such clinical trials. It is now mandatory to register all clinical trials done in India at National Institute of Medical Statistics (NIMS) hosted at Clinical Trial Registry - India (CTRI) website to ensure transparency, accountability and accessibility of clinical trials. This study was planned to analyze the number of clinical trials registered under CTRI from 2007 to 2015. The information regarding the registration of clinical trials was accessed from the website www.ctri.nic.in.
Methods: The information on registered clinical trials was obtained from the website www.ctri.nic.in. The clinical trials registered with CTRI from 2007 to 2015 were noted for analysis.
Results: Maximum number of clinical trials registered in the year 2015 (1113), followed by year 2014 (1089), 2013 (990), 2012 (959) and 2011 (748) while least number of clinical trials registered in the year 2007 (32). Results revealed that there is wide gap the number of clinical trials registered in between year 2007 to 2015 and also revealed that number of clinical trials registered are increasing in order from year 2007 to year 2015.
Conclusions: The registrations of clinical trials improve the reliability of data generated, assist clinicians to interpret research, minimizes duplication of trials and prevents exposure of volunteers to potential risks.

Keywords: Clinical trials, CTRI, DCGI, India

INTRODUCTION

Clinical trials are the gold standard in the field of evidence based medicine. Improvement in therapeutic regimens and advances in medical practice are based on results of clinical trials. Thus results of the clinical trials are useful for the benefit of patients and advances in clinical medicine. Earlier, it would be difficult to find the data and results of various clinical trials. Some clinical trials are abandoned or not published due to "negative" or equivocal results. Thus the availability of only selective information from the clinical trials conducted does not support evidence-based medicine.[1,2] Many researchers are just enthusiastic about publication of either positive or non-inferiority clinical trials and do not publish negative results of the clinical trials. There by distorting the body of evidence available for clinical decision making because this bias reporting of clinical trials. In order to curb the practice of non-reporting of negative clinical trials, International Committee of Medical Journal Editors (ICMJE) proposed mandatory registration of trials at or before the onset of patient enrollment with effect from 1st July 2005.[3-5] ICMJE required to report the clinical trials in accordance to CONSORT statement to increase its scientific value and to increase the chances of publication in high impact journals.[6]

Due to the of presence large treatment-native population and cost-effective trials, the Indian pharmaceutical industries focused on new drug discovery and development which resulted in an increase in the number of clinical trials done in India.[7,8] But such trials were conducted without regulations and necessary ethics approval. To ensure transparency, accountability and accessibility of clinical trials, it is mandatory to register clinical trials in India at Clinical Trial Registry - India (CTRI) website www.ctri.nic.in, hosted by National Institute of Medical Statistics (NIMS).[9,10] This was done mainly to encourage the registration of clinical trials before the enrollment of the first participant. Currently, clinical trials where patient recruitment has started or even completed can also being registered.[11] CTRI is a free and online public record system for registration of clinical trials conducted in India from 20th July 2007. Drug Controller General of India has made it mandatory to register clinical trials at CTRI since 15th June 2009.[11] This study was done to analyze the number of clinical trials registered with CTRI from 2007 to 2015.

METHODS

Data obtained from website Clinical Trial Registry – India (www.ctri.nic.in) for the number of clinical trials registered. Clinical trials registered from the year 2007 to 2015 were noted for analysis. Clinical trials registered in 2016 were excluded from the study. All Clinical trials involving human participants, with drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials being conducted under department of AYUSH were analyzed. Microsoft excel 2013 was used for analysis. Value was expressed as mean±SD. Trend in registration of clinical trials was expressed as line diagram.

RESULTS

The number of clinical trials registered with CTRI between 2007 to 2015 was 6500 as shown in Table 1. The maximum number of clinical trials were registered in the year 2015 (1113), followed by 2014 (1089), 2013 (990), 2012 (959) and 2011 (748) respectively, the least number of clinical trials were registered in the year 2007 (32). Mean±standard deviation for the clinical trials registered was 722.22±390.67.

The results show a significant increase in the number of clinical trials registered from 2007 to 2015. It also shows a sharp rise in the number of clinical trials registered from 2007 to 2010 with slight decrease in 2011 and subsequent rise from 2011 onwards. This changing trend of number of clinical trials registered with CTRI are illustrated in Figure 1.

Table 1: Number of clinical trials registered with CTRI from 2007 to 2015.

Year	Number of clinical trials registered with CTRI
2007	32
2008	155
2009	649
2010	765
2011	748
2012	959
2013	990
2014	1089
2015	1113
Total number (n)	6500
Mean	722.22
Standard deviation (SD)	390.67

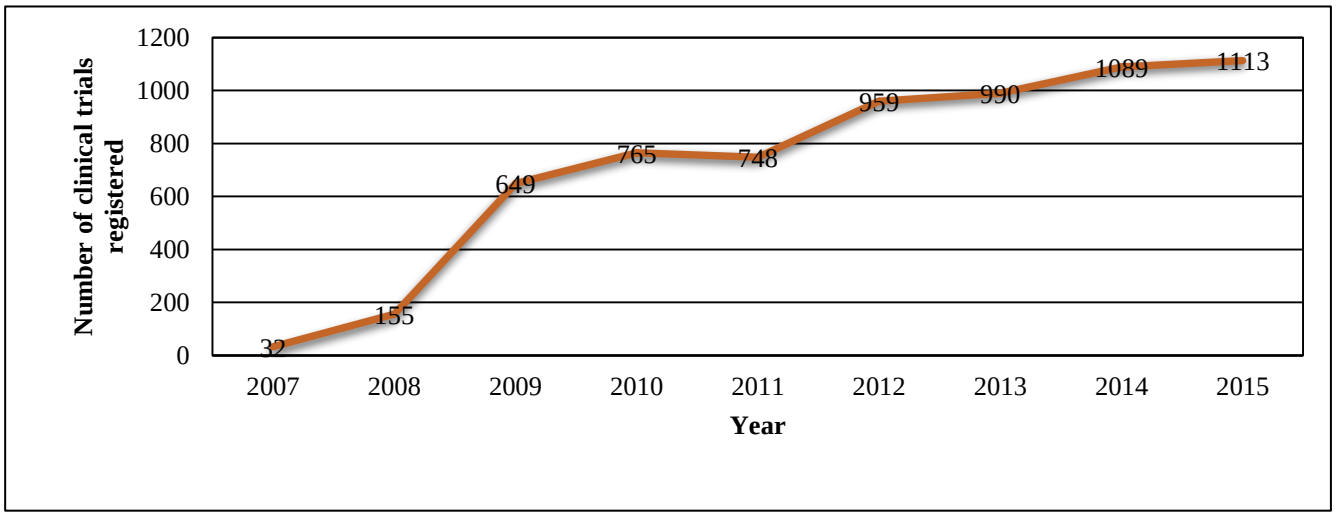

Figure 1: Changing trend of clinical trials registration with CTRI from 2007 to 2015.

DISCUSSION

India promises to be one of the major destinations for the global clinical trials, owing to a huge patient pool, easy recruitment of study participants and low cost of clinical trials. The availability of large drug native patient population and well trained medical professionals has made India an attractive destination for global clinical trials.[10] The registration of clinical trials on the CTRI website www.ctri.nic.in. which was started from 20th July 2007 and DCGI made registration of clinical trials mandatory from 15th June 2009 onwards. Therefore we analyzed the number of registered clinical trials from the year 2007 to 2015. The number of registered clinical trials with CTRI was 6500. Out of this, maximum number of clinical trials registered were in the year 2015 (1113) while least number of clinical trials registered were in the year 2007 (32). This shows that clinical researchers in India are registering their clinical trials with CTRI as per the new regulations of DCGI. It also shows that the new regulations of mandatory registering clinical trials is being implemented in India.[12]

The number of clinical trials registered with CTRI includes all clinical trials completed, terminated and suspended. This mandatory registration by DCGI has made easy availability of all data and reports of all clinical trials done in India. This data and reports consist of positive as well as negative results of the clinical trials done in India. It has been observed that many researchers who were publishing only the positive results of clinical trials in various journals, this mandatory registration of clinical trials with CTRI by DCGI has ensured availability of negative results too.[9] This would be useful for physicians for their clinical decision making as well as for patients preventing them from the exposure of potentially toxic drugs.[13] Many drugs like rimonabant, rosiglitazone, nimesulide and cisapride have been withdrawn from the market by Central Drugs Standard Control Organization (CDSCO) based on the results of post marketing surveillance (PMS) studies.[14]

CONCLUSION

Registration is only part of the means of full transparency with respect to performance and reporting of the results of clinical trials. Research sponsors may argue that public registration of clinical trials will result in unnecessary delays and compromise their competitive edge by allowing competitors full access to their research. Patients who volunteer to participate in clinical trials deserve to know that their contribution to improving human health will be available to physicians. The registration of clinical trials will also help improve the reliability of data generated, help clinicians interpret research in a better way, minimize duplication of trials and prevent exposure of volunteers to potential risks.

The management of the hospital or quality committee had focused on results of this prescription audit. In nut shell we can conclude that the process set by the NABH is the robust one and involvement of clinical pharmacist & pharmacologist for in the prescription audit process is possible which helps the hospital management during accreditation.

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