Analysis of Cardiovascular Trials from Clinical Trial Registry India

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Abstract

Background: Cardiovascular disease (CVDs) are reported as the leading cause of death in the India. The landscape of CVDs CTs are helpful in understanding the trends in progression of R&D and also offer insights of emergence of new technologies over a span of reporting years.

Method: Data was collected for CVDs CTs from database of clinical trial registry India (CTRI) by using keyword "cardiovascular" since 01/01/2008 to 31/08/2017. Data collected for each CTs includes health condition, clinical trial phase (phase I, II, III, IV), study design (randomized/non randomized), type of trials (interventional/observational), study type (drug/ayurveda/medical device/yoga/behavioral) institution type (public/private/partnership), sponsors and monetary support (domestic/international and government/industry/ academia/hospitals), publications (published/not published) and postgraduate thesis (yes/no) and year of registration. Result were analysed in terms of percentage of CTs i.e. n=239 using above mentioned indicators.

Results: The search yielded a total of 239 CTs of which majority of them were found in Phase III (34%) and interventional (69%). Considering the study design, mostly CTs were randomized, parallel group, placebo controlled (25.9%) and conducted in hospitals (29%). For focused health condition, 17.5% associated with diabetes and 15.4% with coronary artery disease. From 2008, 15.8% postgraduate thesis trials had been registered with CTRI but non publication of CTs are highly prevalent. Numerous registered CTs was unclear phase (36%). With regard to type of study, CTs deals with drugs (81%), medical device (19.3%), Ayurveda, yoga, naturopathy and laughing therapy.

Conclusion: The CVDs CTs are low in India and poor access to treatment and out of pocket expenditure are key issues of CVDs management and there is need of effective and inexpensive care with indigenous radical change.

Keywords: Clinical trials, cardiovascular, Clinical trial registry India.