

Trial publication after registration in Clinical Trials Registry of India (CTRI): A cross-sectional analysis of randomized controlled trials

Background:

The Clinical Trials Registry- India (CTRI) is a free and online public record system for registration of clinical trials being conducted in India. From July 2009-Dec 2017, 11052 trials have been registered in CTRI.

Objectives:

We carried out a comprehensive examination of the rates of publication and reporting of results within two years for all completed randomized controlled trials (RCTs) registered in CTRI database.

Methods:

We included trials registered in the CTRI between 15th June 2009 - 15th June 2015. Data from these trials were extracted to identify various aspects (e.g. sponsor, condition studied, study purpose, study type, study phase, number of study arms, intervention model, randomization status, enrolled participants, population, registration, enrolment, trial start and end dates). The identification of the publication status followed a 3-step process; identifying publications from CTRI database, searches using scientific title, short title, and Principal investigator (PI) name on Pubmed, Google Scholar, IndMed and South Asian Database of Clinical Trials databases, and finally-mails were sent to the PI's seeking details of unpublished studies. Relevant publication and non-publication details were further extracted for analysis.

Results:

2949 trials as per inclusion criteria from 5721 RCTS out of a total of 9099 trials registered under CTRI were identified. Out of 2949 studies, publication details (DOI, Citation, ISSN) of 80 (2.7%) studies were mentioned in CTRI. From 2949 studies, 1950 studies were searched and 560 (28.7%) studies were found to be published. 70 studies which were randomly selected from within the 560 studies, revealed that none of the trials had updated the "primary completion date" or "study completion date" in the CTRI website. 1390 (71.3%) out of 1950 studies remain unpublished, 420 studies were available on Medline, no new studies have been identified through contact of principal investigators.

Conclusion:

There is poor publication outputs and noticeable variation in the dissemination of clinical trials results across RCTs registered in CTRI.

Patient or healthcare consumer involvement:

This study is being conducted in collaboration with National Institute of Medical Statistics (NIMS) and Dr. Rao, Director, NIMS is a co-author. NIMS hosts the CTRI database and the study findings is being used to improve reporting of trials registered in CTRI in future.