Original Article

# Landscape of Dental Trials registered in Clinical Trials Registry-India

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## Abstract

**Background:** Evidence-based practice requires clinical trials to be conducted including dental research. In India, if any clinical trial is to be conducted, it is expected to be registered with the Clinical Trials Registry–India (CTRI) as mandated by regulatory bodies, ethics committees, and journal editors. **Aims and Objective:** The present study has been undertaken to assess the type and trends of dental clinical trials being registered with CTRI over a span of 9 years. **Methodology:** For this, dental/dentistry trials were extracted using the keyword "dentistry" from the Study Type section of the CTRI (www.ctri.nic.in). **Results:** The dental trials registration started from just 8 trials in the year 2011 and it has now reached to 400–500 trials from various dentistry disciplines per year. While the registration trends reflect an increase in the number of dental trials registered in CTRI over the years, the number of trials being submitted is low. **Conclusion:** This indicates the need for greater awareness and dissemination at the grassroots level including students and researchers. There is no dearth of dental research and academic institutions in India and the combined efforts of all stakeholders will not only enhance the dental trials registration numbers but also improve the standard of dental research in the country.

**Keywords:** Clinical Trials Registry–India, Clinical Trials Registry–India registration, dental clinical trials

## Introduction

In the initial years of the 21st century, there was a global call for transparency with regard to the conduct of clinical trials as well as to reduce publication bias. In 2004, the International Committee of Medical Journal Editors proposed the comprehensive registration of trials as a condition of consideration for publication.[1] Subsequently, the Clinical Trials Registry–India (CTRI)[2] was launched on July 20, 2007, which offered a platform for the registration of all clinical studies pertaining to all health disciplines including dental research. The CTRI is hosted by the National Institute of Medical Statistics, a premier institute of Indian Council of Medical research.[3] The Drug Controller General of India (DCGI) mandated registration of all regulatory clinical trials prospectively from June 15, 2009. Further, several ethics committees in India also mandated registration of clinical trials for increasing transparency, accountability, and accessibility of clinical trials and their data.[4] Currently, there are more than 31,000 registered records in the CTRI.

**Received:** 13-03-2021 **Revised:** 17-04-2021 **Accepted:** 12-06-2021 **Published:** 02-08-2021

Access this article online

Quick Response Code:

Website: www.jiaphd.org

DOI: 10.4103/jiaphd.jiaphd_37_21

Like any medical research, dental health research is of paramount importance to improve the oral health and overall health of the public. According to the latest report of the Indian National Commission on Macroeconomics and Health, it was estimated that there is a considerable burden of oral disease.[5] With the advent of newer technologies, dental tools, materials, and techniques, research in the field of dentistry is progressing rapidly the world over.[6] With the intention of deciphering the dental research scenario in India and its evolution over the years, an analysis of dental trials registered in the CTRI was undertaken.

### Objective

This study aimed to assess the type and trend of clinical trials registered in the CTRI for the reported study period, i.e. between July 1, 2011, and June 30, 2020.

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**How to cite this article:** Juneja A, Gupta J, Yadav N, Adhikari T, Moulik M, Sharma S, *et al*. Landscape of dental trials registered in clinical trials registry-India. J Indian Assoc Public Health Dent 2021;19:100-3.

## Methodology

The designated study period has been chosen as the CTRI datasets were revised in March 2011. The characteristics of dental trials were extracted from CTRI database using the keyword "Dentistry" from "Study Type" section. By this means, a total of 1411 dental trial records were identified and for each of these records, information (as provided by the registrant) was extracted from the database including the number of trials registered, whether postgraduate (PG) thesis, prospective, or retrospective trial status at the time of registration. In addition, the state-wise and zone-wise distribution of these trials was tabulated and coded from the CTRI database.

Data for the department of specialty according to the Indian Dental Association[7] were manually coded and divided into nine specialties. There were few trials that included multiple specialty departments and others included trials in pharmacology and medical oncology that comprised nonclinical branches. In those trials where departments could not be coded due to lack of clarity on specialization, they were coded as nonspecific and Ayurveda in dentistry.

## Results

### Number of trials registered

A total of 1411 dental trials were registered in CTRI from July 1, 2011, to June 30, 2020. In 2011, only eight dental trials were registered, while 416 trials were registered in 2018. In the year 2020, within a span of 6 months, 255 trials were registered [Figure 1].

### Postgraduate thesis/PhD thesis

PG thesis constituted over 70% ($n$ = 1027/1411) of the registered trials as compared to 384 academic trials, industry-sponsored trials, or investigator-initiated dental trials in medical colleges and research institutes.

### Prospective and retrospective registration

Of the 1411 studies on dental health research, about 64% of trials (904 of 1411) were prospectively registered, i.e., before the enrolment of the first participant into the trial, while 35% ($n$ = 507 of 1411) were registered retrospectively.

### Specialty-wise registration

Majority of the trials ($n$ = 497/1411) registered in CTRI were from periodontics followed by conservative dentistry and endodontics ($n$ = 202/1411), orthodontics and dentofacial orthopedics ($n$ = 156/1411), while $n$ = 146/1411 were from pediatric and preventive dentistry. Of the remaining trials, 48 trials could not be categorized due to lack of clarity in specializations, five trials were conducted in multiple specialties, while six trials were categorized as "Others" which included trials from medical oncology, nonclinical branches, and oral genetic department [Figure 2].

Positive growth over the years in the department of endodontics and conservative, department of public health dentistry, and department of periodontics was observed, as shown in Figure 2.

### States and region

More than 50% of the registered trials were from the southern region. The highest number of trials registered in CTRI was conducted in Karnataka ($n$ = 350/1411), followed by Maharashtra ($n$ = 203/1411), Tamil Nadu ($n$ = 175/1411), Uttar Pradesh ($n$ = 132/1411), New Delhi ($n$ = 73/1411), and Haryana ($n$ = 62/1411). The number of dental institutions state-wise and the number of dental trials in the respective states are given in Map, as shown in Figure 3.

## Discussion

Oral health is an essential component and indicator of the overall health and well-being of an individual.[8] There are more than 308 dental colleges in India, which is among highest in the world and can be better utilized to prioritize and manage oral health in India and also enhance the magnitude of much-needed research in the field of dentistry.

Clinical trials are conducted to generate research evidence and registration. The safety and efficacy of any drug or procedure is determined through the conduct of clinical trials, that's why evidence-based practice and tracking of research is essential.[9] It is evident from the findings that the dental trial registration is also low and considering the number of dental colleges in the country, there is considerable scope in terms of enhancing trial registration numbers from this discipline. Evidently, there is a need to prioritize the importance of dental research in the country. This study was initiated with the intention of obtaining a real-world view of the dental research trends in the country vis-à-vis the actual number of colleges in each state and distribution therein.

The growth in health-care industry in dentistry is evident from the gradual increase in the number of dental clinical trials over the years, but the actual number of registrations may still be less in terms of trials being conducted in the country, and this emphasizes the need for awareness and promotion of prospective registrations.

In 2016–2017, CTRI conducted various workshops in medical colleges and institutes throughout the country to increase awareness at the grass-root level to enable more quality research work. Along with that, the support of the DCGI,[4] ethics committee, and the journal editors[1] to promote and enforce registration may be one of the major impetuses to confer a consistent increment in PG thesis. This was an encouraging finding. Although the quality of dental trials is a matter of concern, this may be improved by training the researchers and the students with the principles of clinical research methodologies. Considering the number of dental colleges in the country, there could be scope in terms of improving trial registration in this area.

The number of retrospective dental trial registrations in the CTRI had declined over the years. CTRI since its inception registered all retrospective and prospective trials. The CTRI in April 2018 implemented a policy change which mandated

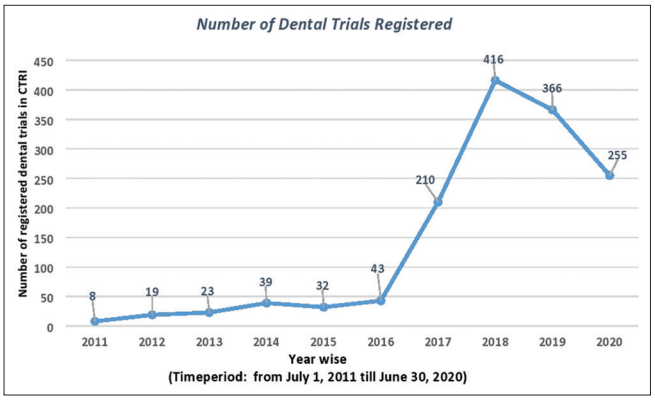


**Figure 1:** Number of dental trials registered in Clinical Trials Registry–India over the years

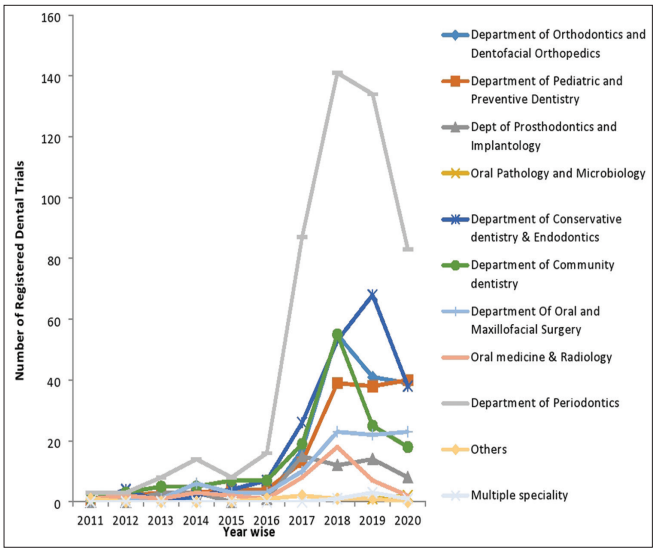


**Figure 2:** Department-wise number of registered dental trials in Clinical Trials Registry–India

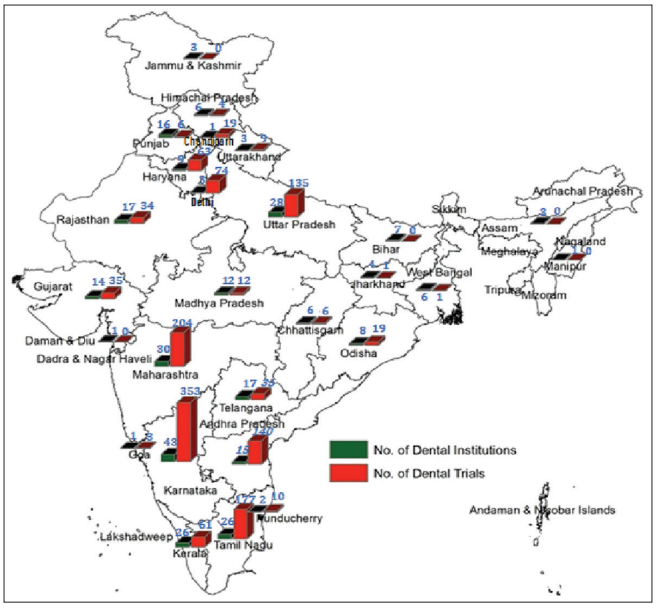


**Figure 3:** State-wise Number of dental institutes and registered trials

only prospective registrations to minimize the publication bias and improve the transparency in conduct of the clinical research.[2] After enforcement of this policy, a decrease in dental trials registered is observed. Along with the policy of prospective registration, the mandate of the recommendation of all institutional ethics committees and statement by the journal editors to impose prospective registration as a precondition to consideration for publication will definitely help in further improving the quality research in the near future.[1]

The CTRI database is a huge resource for researchers and patients. Dental research is progressing rapidly which has resulted into distinct oral health specializations to combat different oral health issues such as orthodontics, periodontics, pedodontics, prosthodontics, endodontics, oral and maxillo-facial surgery, cosmetic and esthetic dentistry, oral pathology, forensic dentistry, oral medicine, crown and bridge dentistry, preventive dentistry, operative dentistry, implant dentistry, and public health dentistry. Dental research is progressing rapidly which has resulted in distinct oral health specializations to combat different oral health issues in dental specialties.[7] The awareness regarding various dental specialties among the dental interns, and the general public, including doctors, is very low. A general dentist is not well equipped to deal with all oral health issues. A recent study found that a large number of interns are not aware of the differences among the branches in dentistry.[10] With the registration of more dental trials, awareness is bound to rise not only in the general public but also in the medical fraternity, including dental students to help them make informed and appropriate decision regarding their future specialization. CTRI database gives information about the dental issues, specialties, and procedures, on which the dental research is being conducted in the country. This valuable information on dental issues, research going on in the country to cater to these issues and the gaps in the research, could be helpful in directing future research.[11,12]

There are 308 dental colleges in India out of which 87% ($n$ = 292/332) are private institutes which are indicative of concern and improvement in oral health care, but this also reflects that there is a limited support for research and development by the government in the field of dentistry.[11,12] This is encouragingly being reflected in current policies of the government in this field.[13] As per the analysis, majority of dental trials (55%) are conducted in the South Zone in which Karnataka, Maharashtra, and Tamil Nadu are the major contributors followed by north zone sites Uttar Pradesh, Delhi, and Haryana. Establishing the government dental research institutes and hospitals in the under-served areas will support dental research among young researchers and will enhance evidence-based practice.

## Conclusion

It may be concluded that clinical trial registration has strong potential to contribute substantially to improve transparency, accessibility, and accountability of clinical research and their data as wella s reducing the publication bias, in medical as well as dental research. Currently, this may not be to the desired level but can be further promoted through the dissemination activities, workshops, conferences, newsletters, etc., to the different regions of the country. Undoubtedly, the engagement with various stakeholders has impacted the increase in dental trials during recent years. The switching over to the prospective system of registration now demands planning and documenting the trials even before its initiation. In addition, methodological training workshops can help clarify research aspects and help raise the standard of research that would enable better publication rates in this sector of medical research as well.

### Acknowledgment

We gratefully acknowledge the encouragement and continuous support by the entire CTRI team.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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