

FEATURE ARTICLE

CLINICAL TRIALS IN DENTISTRY: A CROSS-SECTIONAL ANALYSIS OF WORLD HEALTH ORGANIZATION-INTERNATIONAL CLINICAL TRIAL REGISTRY PLATFORM

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ABSTRACT

Introduction

Clinical trials are the back bone for evidence-based practice (EBP) and recently EBP has been considered the best source of treatment strategies available. Clinical trial registries serve as databases of clinical trials. As regards to dentistry in specific data on the number of clinical trials and their quality is lacking. Hence, the present study was envisaged.

Method

Clinical trials registered in WHO-ICTRP (<http://apps.who.int/trialsearch/AdvSearch.aspx>) in dental specialties were considered. The details assessed from the collected trials include: Type of sponsors; Health condition; Recruitment status; Study design; randomization, method of randomization and allocation concealment; Single or multi-centric; Retrospective or prospective registration; and Publication status in case of completed studies.

Results

A total of 197 trials were identified. Maximum trials were from United States ($n = 30$) and United Kingdom ($n = 38$). Seventy six trials were registered in Clinical Trials.gov, 54 from International Standards of Reporting Clinical Trials, 13 each from Australia and New Zealand Trial Register and Iranian Registry of Clinical Trials, 10 from German Clinical Trial Registry, eight each from Brazilian Clinical Trial Registry and Nederland's Trial Register, seven from Japan Clinical Trial Registry, six from Clinical Trial Registry of India and two from Hong Kong Clinical Trial Registry. A total of 78.7% studies were investigator-initiated and 64% were completed while 3% were terminated. Nearly four-fifths of the registered trials (81.7%) were interventional studies of which randomized were the large majority (94.4%) with 63.2% being open label, 20.4% using single blinding technique and 16.4% were doubled blinded.

Conclusion

The number, methodology and the characteristics of clinical trials in dentistry have been noted to be poor especially in terms of being conducted multi-centrally, employing blinding and the method for randomization and allocation concealment. More emphasis has to be laid down on the quality of trials being conducted in order to provide justice in the name of EBP.

INTRODUCTION

Clinical trials which are considered to be the back bone of EBP (Evidence Based Practice) generate very high quality evidence. These are the evidences that get incorporated into literature which is available to generate quality practice.¹ The thrust finally lies in the way the trials are being conducted which needs careful attention. This is why recording of trials in a clinical registry platform becomes important. There exists a wide range of clinical trial registry platforms round the world one of which is the World Health Organization International Clinical Trial Registry Platform (WHO-ICTRP) initiated in 2006.²

Studies conducted on these registries in the medical and allied medical fields^{3,4} yielded results which included poor quality of reporting clinical trials⁵ in general. As regards to dentistry the same exists⁶ and also there is paucity of available data regarding the methodology as well. A study conducted by same authors on the clinical trials in India as regards to dentistry also reported poor quality of trials. Hence, the present study was initiated with an objective to obtain a holistic view of methodological quality and trends of clinical trials done in all these fields.

METHOD

The study was conducted between September 2014 and January 2015. The key word 'dental' was used in the "Intervention" section to search the trial website WHO-ICTRP (<http://apps.who.int/trialsearch/AdvSearch.aspx>). No limit in either the recruiting status or date of registration was placed. Both the authors independently were involved in retrieving and analyzing the studies obtained. Duplicate studies were checked and omitted.

The following details were assessed for: Source of primary registry [Clinical Trial Registry of India (CTRI), Chinese Clinical Trial Registry (ChiCTR), Korean Clinical Trial Registry (KCT), Clinical trials.gov (CTG), German Clinical Trials Register (GermanCTR); International Standards of Reporting Clinical Trials (ISRCTN), Nederland's Trial Register (NTR), European Clinical Trial Database (EudraCT), Brazilian Clinical Trial Registry (REBEC), Iranian Registry of Clinical Trials (IRCT), Hong Kong Clinical Trial Register (HKCTR), Australia and New Zealand Trial Register (ANZTR), Japan Clinical Trial Registry (UMIN-CTR)]; Type of sponsors (academic or commercial); Health condition; Year of registration; Institutional Ethics Committee (IEC) approval; Recruitment status (ongoing/completed); Study design {observational/interventional [non-randomized/randomized (open label, single blind, double blind)]}; randomization, method of randomization [Computer Generated (CG), Random Number Table (RNT)] and allocation concealment; Phase of clinical trials (I, II, III and IV); Single or multi-centric; Type of study

Table 1. Subjects of interest for clinical trials in dentistry (N = 197).

Dental condition	Number of studies (%)
Oral health in medically compromised patients	34 (17.3)
Orthodontics and malocclusion	23 (11.7)
Gingivitis/periodontitis	23 (11.7)
Dental caries	20 (10.2)
Analgesics and antibiotic use in dentistry	10 (5.1)
Acupuncture	1 (0.5)
Removable partial dentures	4 (2)
Acid etching and bonding	6 (3)
Dental sedation	4 (2)
Extraction and fractures (oral surgical)	9 (4.5)
Gagging	2 (1)
Fluoride	6 (3)
Public health	11 (5.5)
Capnography	1 (0.5)
Impression materials	1 (0.5)
Enamel remineralization	3 (1.5)
Tooth brushing	4 (2)
Oral health in geriatrics	3 (1.5)
Probiotics	6 (3)
Resorbed mandible	1 (0.5)
Dentin hypersensitivity	3 (1.5)
Myofacial pain dysfunction syndrome	1 (0.5)
Saliva and xerostomia	3 (1.5)
Enamel remineralization	2 (1)
Pulp capping	3 (1.5)

(continued)

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