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# Analysis of AYUSH studies registered in clinical trials registry of India from 2009 to 2020



J-AIM

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#### A R T I C L E I N F O

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Keywords: Siddha Clinical Trials Registry—India AYUSH clinical trials Randomized controlled trial ABSTRACT

*Background:* The Clinical Trials Registry—India (CTRI) is an initiative of the Indian Council of Medical Research, New Delhi, India (ICMR) and monitored by the ICMR-National Institute of Medical Statistics (NIMS) since July 20, 2007. Randomized clinical trials are considered as the gold standard in evidence-based medicine. Registration of clinical trials enables disseminating evidence among clinicians, researchers, and patients. It promotes transparency and avoids duplication. The registration process is mandatory for AYUSH clinical trials also.

*Objectives:* This analysis is aimed to determine the different characteristics of registered AYUSH clinical trials in CTRI from 2009 to 2020.

*Materials and methods:* A cross-sectional retrospective analysis was conducted. The information on registered clinical trials about AYUSH was obtained from the website www.ctri.nic.in from 2009 to 2020 (n = 3632; last accessed on July 30 2020). Data analysis considered the following factors for analysis using descriptive statistics. The number of clinical trials registered in AYUSH stream were classified according to registration type (retrospective/prospective), postgraduate dissertations (yes/no), primary sponsor, type of trial (interventional/observational), study design, health condition and State-wise distribution of sites of studies.

*Results:* The number of clinical trial registrations among AYUSH streams (3632) descends from Ayurveda (2054), followed by Siddha (635), Yoga (408), Unani (366) and Homoeopathy (169). Interventional studies dominate observational studies among all AYUSH registered trials. AYUSH streams took four years to register in CTRI due to an increase in reporting trials from 2013. Significant number of trials were registered retrospectively. The order of closure of retrospective registration has influenced an increase in prospective enrolment between 2017–2019.

*Conclusion:* Registration of clinical trials in the CTRI should be encouraged. Randomized controlled trials (RCTs) occupy a rear seat which exposes an opportunity for trials and alarms about weak trials. Noncommunicable diseases (NCDs) are registered more comparatively, which reflects the strength of AYUSH in NCDs. Most of the trials fall under phase 2, which seems to have an increasing opportunity for more trials. Certain visible flaws like registering Phase 2 trials as Phase 3 or 4 and domestic trials as international trials reflect human resources crunch in ICMR-CTRI in Issuing Certificates. These errors should be rectified by training the stakeholders effectively.

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#### 1. Introduction

The Clinical Trials Registry—India (CTRI) is a free and online public record domain for registration of clinical trials conducted in

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India from July 20, 2007. The Drug Controller General of India has made it mandatory to register clinical trials at CTRI since June 15, 2009. Clinical trials are regarded as the gold standard in evidencebased medicine. Registering clinical trials is a contemporary issue for the present health researcher [1]. According to the World Health Organization – International Clinical Trials Registry Platform (WHO-ICTRP), the registration of all interventional trials was considered as scientific, ethical, and moral responsibility and it had also led to possibilities in identifying potential problems early in the research

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Table 1				
Year-wise	registration	AYUSH	clinical	studies.

Year-wise registrat	Year-wise registration AYUSH clinical studies						
Year\Group	Ayurveda	Yoga	Unani	Siddha	Homeopathy	Total	
2008	0(0)	2(0.06)	0(0)	1(0.03)	2(0.06)	5(0.14)	
2009	0(0)	4(0.11)	3(0.08)	0(0)	1(0.03)	8(0.22)	
2010	3(0.08)	7(0.19)	5(0.14)	1(0.03)	0(0)	16(0.44)	
2011	36(0.99)	15(0.41)	3(0.08)	3(0.08)	15(0.41)	72(1.98)	
2012	53(1.46)	14(0.39)	4(0.11)	2(0.06)	15(0.41)	88(2.42)	
2013	55(1.51)	13(0.36)	15(0.41)	7(0.19)	11(0.3)	101(2.78)	
2014	54(1.49)	9(0.25)	6(0.17)	42(1.16)	10(0.28)	121(3.33)	
2015	93(2.56)	14(0.39)	30(0.83)	19(0.52)	4(0.11)	160(4.41)	
2016	116(3.19)	13(0.36)	3(0.08)	15(0.41)	4(0.11)	151(4.16)	
2017	297(8.18)	70(1.93)	35(0.96)	100(2.75)	27(0.74)	529(14.56)	
2018	497(13.68)	105(2.89)	108(2.97)	194(5.34)	50(1.38)	954(26.27)	
2019	655(18.03)	79(2.18)	72(1.98)	164(4.52)	18(0.5)	988(27.2)	
2020	195(5.37)	63(1.73)	82(2.26)	87(2.4)	12(0.33)	439(12.09)	
Total	2054(56.55)	408(11.23)	366(10.08)	635(17.48)	169(4.65)	3632(100)	

process [2]. The first clinical trial registry was introduced 30 years ago to track all clinical trials initiated at that time and helped to retrieve information about unpublished clinical trials, as well [3,4]. The unethical behaviour of few pharmaceutical agencies with regards to medical trials was also detected [5]. Since India has a sizeable native population, Indian pharmaceutical industries focus on new drug discovery and development for cost-effective trials, which would help to increase the number of clinical trials in India [6,7]. However, it is reported that some trials were conducted in an unethical manner without any regulations and do not hold any ethical approval [8,9]. Hence, for transparency, responsibility, and convenience of clinical trials, it is mandatory to register them in India at CTRI as this will be advantageous for patients and will also help advancement of medicine. Previously, it was hard to find the data and results of various clinical trials conducted. Some clinical trials were abandoned or not published due to undesirable or ambiguous effects. Thus, the accessibility of only selective evidence from the clinical trials conducted does not support evidence-based medicine [10,11]. Various researchers are just passionate about publication regardless of positive or non-inferiority clinical trials. The publishers ignore to publish negative results and misinterpret the frame of evidence. To control the practice of non-reporting of negative clinical trials, CTRI proposed mandatory registration of trials at or before the onset of patient enrolment with effect from June 15, 2009.

The CTRI recommends registering clinical trials before the enrolment of the first study participant. However, currently the trials are accepted where patient recruitment has started or even completed (retrospective registration). Though CTRI receives retrospective registration, only prospective registered trials are linked with WHO-ICTRP [12]. Further, from April 1, 2018, the CTRI moved towards the prospective trial registration, and accepted the

Table 2	
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Registration of the studies.

clinical studies for registration that had not vet begun in enrolling patients. It would be applicable for all types of AYUSH - BA/BE (Bioavailability and Bioequivalence), PMS (Post-marketing surveillance), postgraduate dissertations, and clinical studies submitted for registration. Prospective registration of clinical trials avoids discriminating reporting or altering primary outcomes and selective publication, preventing duplication of efforts helping researchers, funders, and ethics committees, and helps during peer review to understand the context of study results. In CTRI, only limited data are available for AYUSH clinical trials. The present paper reports the analyses of AYUSH clinical trials registered in CTRI. The primary objective of these analyses was to determine the proportion of number of clinical trials registered in AYUSH systems, registration type (retrospective/prospective), postgraduate dissertations (yes/no), primary sponsor, type of trial (interventional/ observational), study design, health condition and State-wise distribution of sites registered in AYUSH clinical trials.

## 2. Materials and Methods

A cross-sectional study of AYUSH clinical trials was registered on CTRI. The data for the number of clinical trials registered was obtained from the CTRI website (www.ctri.nic.in). Clinical trials registered on the CTRI registry that were downloaded from 2009 to 2020 (n = 3632; last accessed on July 30 2020) were taken for analyses. The searched terms used were Siddha, Ayurveda, Unani, Yoga, Naturopathy, Homeopathy, CTRI/YYYY (year to be specified). All clinical trials involving human participants, with or without drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioural treatment, rehabilitation approaches, and trials being conducted under the department of AYUSH were taken for study. Excel spreadsheet was used for data

Registration	Registration of the studies							
		Ayurveda	Yoga	Unani	Siddha	Homeopathy	Total	
Phase	Phase 1	176(4.85)	34(0.94)	2(0.06)	15(0.41)	10(0.28)	237(6.53)	
	Phase 2	502(13.82)	49(1.35)	245(6.75)	361(9.94)	33(0.91)	1190(32.76)	
	Phase 3	197(5.42)	29(0.8)	54(1.49)	57(1.57)	38(1.05)	375(10.32)	
	Phase 4	79(2.18)	12(0.33)	4(0.11)	5(0.14)	5(0.14)	105(2.89)	
	NA	1100(30.29)	284(7.82)	61(1.68)	197(5.42)	83(2.29)	1725(47.49)	
Total		2054(56.55)	408(11.23)	366(10.08)	635(17.48)	169(4.65)	3632(100)	
Туре	Prospective	1391(38.3)	270(7.43)	232(6.39)	444(12.22)	101(2.78)	2438(67.13)	
	Retrospective	661(18.2)	138(3.8)	134(3.69)	190(5.23)	68(1.87)	1191(32.79)	
	NA	2(0.06)	0(0)	0(0)	1(0.03)	0(0)	3(0.08)	
Total		2054(56.55)	408(11.23)	366(10.08)	635(17.48)	169(4.65)	3632(100)	

Table 3				
Research	design	of	registered	studies.

Research design of regis	Research design of registered studies							
Study Design	Ayurveda	Yoga	Unani	Siddha	Homeopathy	Total		
Randomized	1212(33.37)	294(8.09)	149(4.1)	31(0.85)	96(2.64)	1782(49.06)		
Non-Randomized	48(1.32)	15(0.41)	9(0.25)	39(1.07)	6(0.17)	117(3.22)		
Single Arm Trial	570(15.69)	43(1.18)	187(5.15)	366(10.08)	64(1.76)	1230(33.87)		
Other	224(6.17)	56(1.54)	21(0.58)	199(5.48)	3(0.08)	503(13.85)		
Total	2054(56.55)	408(11.23)	366(10.08)	635(17.48)	169(4.65)	3632(100)		

collection. Data pertaining to the study objectives were collected for the analyses. For effective analysis, the variables were divided into qualitative and quantitative. Qualitative analysis of CTRI was done through variables such as trial design, phases of the clinical trial, type of trial (interventional/observational), type of study design and health condition. Quantitative variables included number of trial registration, year-wise and State-wise distribution of studies, number of postgraduate dissertations, and type of sponsorship. Ethical approval for this study is not mandatory, as this study did not involve any human participants; only data is verified.

## 3. Results

Between the period 2009 to July 30, 2020, a total of 27,075 trials were registered. The registered number of clinical trials by AYUSH professionals were 3632 (13.4%) as of July 30, 2020. The outcomes of the trials were recorded as Ayurveda 2054 (56.55%), Siddha 635 (17.48%), Yoga 408 (11.23%), Unani 366(10.08%) and Homeopathy 169 (4.65%) (Table 1). Siddha clinical trials registration increased from 0.03% in 2008 to 4.52% in 2019 while Ayurveda trials increased from 0.08% in 2010 to 18.03% in 2019. A similar increasing trend was noted in Unani, Yoga and Homeopathy. In Siddha, out of 635 registrations, 80% were postgraduate dissertations. Similarly, in Ayurveda out of 2054, 75.02% registrations belonged to postgraduate dissertations while over 50% of Unani and Yoga registrations were postgraduate dissertations papers. In Homeopathy, 79.88% of the registered trials were non-postgraduate and only 20.12% belonged to postgraduate dissertations. In comprehensive studies, 69.92% Siddha papers were registered prospectively. Similarly, 67.72% trials were registered prospectively in Ayurveda, 66.18% in Yoga and 63.39% in Unani. In Homoeopathy, 59.76% trials were registered prospectively. The prospective registrations of AYUSH clinical trials increased from 2014 (Table 2). When the study design was assessed, the results revealed that 72.06% Yoga trials were randomized clinical trials, followed by Ayurveda (59.01%), Unani (40.71%), Homeopathy (56.8%), and Siddha (4.88%). Out of the total number of trials, 57.64% in Siddha were single-arm studies, while 37.87% were in Homoeopathy. In Homeopathy, 3.55% trials were non-randomized (Table 3). Interventional Studies showed a gradual decrease in the following order - Unani (96.45%), Yoga (96.08%), Homeopathy (90.53%), Ayurveda (90.9%), and Siddha (70.08%) (Table 4). Most of

Table	4
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Intervention of registered studies.

the trials were focused on patients, and only 10% or less involved healthy individuals. AYUSH systems focus mainly on non-communicable diseases in specific clinical trials (Table 5). Government research funding agencies and Government medical colleges cover over 75% trials in all AYUSH streams. Contribution from industrial research is meagre in all streams; however, the highest is in Ayurveda (5.45%) (Table 6). Statistically, Siddha system has been widely followed in the southern part of India, especially in Tamil Nadu (98.27%). The top 10 States contributing to the AYUSH streams were also analysed and it was observed that, few states did not contribute towards AYUSH streams; initiatives should be taken to promote such streams (Supplementary Table, S1) (see Table 2).

# 4. Discussion

At the closing date of this study, i.e., July 30, 2020, the total number of trials registered in CTRI were 3632. From the start date, i.e., in 2009, the number of trials registered in the AYUSH category was only nine. There is a definite escalation in the registration followed by the order of CTRI (office order F No 12–01/09-DC- [Pt 32]). Traditional Chinese Medicine (TCM) has also encountered escalation in registration of clinical trials between 2005 (n = 83) to 2017 (n = 755). This may be due to the mandate of registering trials in any of the public trials registry. Acupuncture occupies the highest number in TCM registries, followed by Chinese herbal medicines. Also, a similar phenomenon exists in CTRI among the registered AYUSH data. Ayurveda has registered more than 50% of the trials followed by Siddha, Yoga, Unani, and Homeopathy in descending order.

The CTRI mission was to encourage all clinical trials conducted in India and to be prospectively registered, i.e., before the enrolment of the first participant [14]. However, 21% of the AYUSH studies were registered retrospectively, and in TCM, it was 39% [13]. CTRI decided to register only the prospective trials and this action alarmed the clinicians who wished to register. However, the time between the announcement and the end-date has embarked much on retrospective registration. Prospective registration had increased the transparency of the trials and non-redundancy. It had also helped in the increased the number of trials. Siddha, Ayurveda, and Unani have an increased number of prospective registrations on par with Homeopathy and Unani. Though certain studies have

Intervention of registered studies							
Type of Trial	Ayurveda	Yoga	Unani	Siddha	Homeopathy	Total	
Interventional	1867(51.4)	392(10.79)	353(9.72)	445(12.25)	153(4.21)	3210(88.38)	
Observational	179(4.93)	15(0.41)	13(0.36)	189(5.2)	15(0.41)	411(11.32)	
BA/BE	2(0.06)	0(0)	0(0)	0(0)	1(0.03)	3(0.08)	
PMS	6(0.17)	1(0.03)	0(0)	0(0)	0(0)	7(0.19)	
NA	0(0)	0(0)	0(0)	1(0.03)	0(0)	1(0.03)	
Total	2054(56.55)	408(11.23)	366(10.08)	635(17.48)	169(4.65)	3632(100)	

Table 5	;
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Health conditions studied.

Health conditions studied

		Ayurveda	Yoga	Unani	Siddha	Homeopathy	Total
Health Condition	Healthy Patient Healthy & Patient NA	46(1.27) 2007(55.26) 1(0.03) 0(0)	51(1.4) 350(9.64) 7(0.19) 0(0)	10(0.28) 351(9.66) 5(0.14) 0(0)	20(0.55) 604(16.63) 10(0.28) 1(0.03)	20(0.55) 147(4.05) 2(0.06) 0(0)	147(4.05) 3459(95.24) 25(0.69) 1(0.03)
Total Communicable v/s Non communicable	Communicable Non - Communicable RMNCH Othore	2054(56.55) 100(2.75) 1894(52.15) 44(1.21) 16(0.44)	408(11.23) 19(0.52) 322(8.87) 13(0.36)	366(10.08) 31(0.85) 253(6.97) 55(1.51) 27(0.74)	635(17.48) 55(1.51) 513(14.12) 22(0.61) 45(1.24)	169(4.65) 23(0.63) 101(2.78) 16(0.44) 20(0.8)	3632(100) 228(6.28) 3083(84.88) 150(4.13) 171(4.71)
Total	others	2054(56.55)	408(11.23)	366(10.08)	635(17.48)	169(4.65)	3632(100)

RMNCH: Reproductive, maternal, new-born and child health.

indicated otherwise, uncontrolled trials may prove the efficacy of the drug.

The same should be followed in rigorous controlled trials to prove the efficacy of AYUSH globally [15]. Therapeutic exploratory studies confirm the AYUSH community's new opportunity reflected via the numbers in Phase II trials (n = 1190 (32.76%)). A therapeutic confirmatory trial follows the therapeutic exploratory trial. The same was reflected in the number of trials in the Phase III stage (n = 375 (10.32%)). Among the trial designs, Phase IV studies were minimum with 2.89% in AYUSH whereas 8% in TCM [16]. Interventional studies showed a gradual decrease, and were ordered ascendingly as Yoga (96.08%), Unani (96.45%), Ayurveda (90.90%), Homeopathy (90.53%) and Siddha (70.08%). In public health approaches, observational studies have played a primary role, which helped Siddha to reach 29.76%. The safety of the study is vital in any trial.

Government funding agencies and Government medical colleges cover more than 75% in all AYUSH streams, whereas in TCM, hospitals and universities play a significant role in funding. Industry-sponsored clinical trials are 5% in TCM, while 3.49% in AYUSH. Private colleges stand next to the government agencies in registering. However, registrations done by domestic and international pharmaceutical companies are very less among AYUSH systems except, Ayurveda. Increased number of clinical trials by industries will yield more confidence to the regulators and for the end-users i.e., physicians. A significant rise in industrial funding may bring out quality products. Registration of observational studies is not mandatory (both by CTRI and ICMJE) as the intervention in observational studies is not recommended by the

Table 6	
Primary sponsor of registered studies.	

researchers. In the present study, 11.32% of observational studies were registered in total. This shows increasing interest in registering observational studies though it seems to be minimal. The safety of the study is vital in any trial. AYUSH practitioners shoulder the responsibilities in non-communicable disease management. which is evident as the number of clinical trials registered are at a higher (84.88%) rate. Based on the trials registered, it could be assumed that many trials were registered under the non-communicable disease category before COVID19. It is also in alliance with the WHO-ICTRP [17]. Siddha system is concentrated in South India, especially in Tamil Nadu [18]. Siddha is confined to a very small population though it is very effective and initiatives should be undertaken to establish Siddha to reach people and benefit them in different parts of the world. Among 10 states mentioned in the Supplementary Table S1, no contributions were offered from few states which should be noted by concerned people and effective steps should be taken for its establishments.

# 5. Conclusion

Registering in CTRI will increase the internal validity and transparency. The notice issued by CTRI regarding prospective registration has regulated the registration process. The publication of AYUSH-GCP guidelines has helped a lot in research conduct. Postgraduate registrations are on par with the number of colleges and postgraduate seats. A rise in controlled trials will elevate visibility of AYUSH globally. National Health Policy, 2017 has recognised the strength of AYUSH. The study revealed the fact that a number of clinical trials of AYUSH fall under the category of non-communicable

Primary sponsor of registered studies							
Sponsor	Ayurveda	Yoga	Unani	Siddha	Homeopathy	Total	
GFA	991(27.29)	225(6.19)	298(8.2)	344(9.47)	66(1.82)	1924(52.97)	
GMC	220(6.06)	37(1.02)	13(0.36)	184(5.07)	63(1.73)	517(14.23)	
Global - Pharma	19(0.52)	1(0.03)	4(0.11)	0(0)	1(0.03)	25(0.69)	
Indian- Pharma	93(2.56)	1(0.03)	9(0.25)	5(0.14)	3(0.08)	111(3.06)	
Pvt Hospital/Clinic	19(0.52)	10(0.28)	2(0.06)	1(0.03)	11(0.3)	43(1.18)	
Pvt College	323(8.89)	18(0.5)	8(0.22)	0(0)	12(0.33)	361(9.94)	
Other	387(10.66)	115(3.17)	32(0.88)	101(2.78)	13(0.36)	648(17.84)	
NA	2(0.06)	1(0.03)	0(0)	0(0)	0(0)	3(0.08)	
Total	2054(56.55)	408(11.23)	366(10.08)	635(17.48)	169(4.65)	3632(100)	

GFA: Government Funding Agency.

GMC: Government Medical College.

Global - Pharma: Pharmaceutical Industry-Global.

Indian- Pharma: Pharmaceutical Industry-Indian.

Pvt Hospital/Clinic: Private Hospital/Clinic.

Pvt College: Private Medical College.

diseases. There is a scope to increase Phase III and IV studies in AYUSH. Industries should increase their investments for performing research in clinical trials. International regulatory bodies like FDA, EMA will ensure the GCP for global acceptance. The investigators may choose a wrong column (for example, instead of Phase II, they selected Phase III) when they perform a clinical trial, and these errors can be rectified by training the stakeholders effectively.

### Source(s) of funding

None.

#### **Conflict of interest**

None.

#### Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jaim.2021.04.004.

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