



The Awareness Survey of Clinical Trials Among Medical Students of South Rajasthan, India

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Abstract

Background / Aim: Clinical trials are becoming more popular in India, but its awareness among the medical professionals remains far from satisfactory. Clinical research/trial can help medical students in developing the critical thinking abilities necessary for medical practice. In this era of evidence-based medicine, the integration of medical education and clinical research is crucial to ensure that scientific findings are translated into clinical practice. The present study aimed to find out the awareness about clinical trial among undergraduates.

Methods: After obtaining approval from the Institutional Ethics Committee, this cross-sectional study was conducted on students from first to final year and interns after taking their consent. A sample of 390 respondents was analysed. A structured questionnaire was used to measure the objective of this study. The proportion of successfully answered questions in each group was computed and the results were sorted into pre-determined grades as follows: As excellent - 80-100 %, moderate - 50-80 % and terrible - less than 50 %.

Results: Out of 390 undergraduate students, for the statement regarding the concept of clinical trials, around 28.2 % fell in the good category, 57.7 % in the average category and 14.1 % in the poor category. Regarding the statement about role of the United States Food and Drug Administration (US FDA) in approving new drug, 34.1 % were poor responders, 52.6 % were average and 13.3 % were good. The statements regarding the participation in the clinical research study showed that majority were in the poor and average response category (45.6 % and 41.5 %, respectively) as compared to only 12.8 % in the good category.

Conclusions: The overall awareness of clinical trials was low among students, the medical undergraduates are future innovators, clinicians and scientific explorers. It would be better if they are trained at earlier days of learning about clinical trials/research and medical ethics. These can be made a part of medical curriculum so that they can build their concrete future.

Key words: Clinical trials; Knowledge; Undergraduate medical students; Awareness.

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Introduction

Clinical trials have a significant role in improving the quality of healthcare practice in a timely manner.¹ These trials are conducted at the majority of teaching medical institutes. The numerous steps of clinical trials, the process of putting together a study and giving the patient informed consent are included in the pharmacology curriculum for

medical students at the undergraduate level.² Undergraduate medical students can be benefitted from basic research in order to strengthen their critical thinking skills, which are necessary for medical practice. The integration of medical education with clinical research is critical in this era of evidence-based medicine to see that scientific



breakthroughs are translated into therapeutic practice. Teaching medical students about clinical research and trials may motivate some of them to seek a career in clinical trials and some of them may even participate in clinical trials.³ The purpose of this study was to see how well undergraduate medical students knew about clinical trials in the Government Medical College, Kota, Rajasthan, India.

Methods

The research was done on undergraduate medical students in a cross-sectional study during the month of February 2020, after acquiring clearance from the Government Medical College's Institutional Ethics Committee in Kota, Rajasthan, India. After receiving their consent, a pre-tested questionnaire was used to interview the participants in this study. Medical students of first to final year, as well as interns, were given the questionnaire. Before the study began, the main investigator explained the study's purpose and obtained signed consent from the participants. The participants were also told that participation in the interview was completely optional and that they might leave at any time. All information acquired from participants was kept confidential. Participants who refused to participate in the study were excluded from the study.

A questionnaire was used in a similar study conducted by Vittalrao et al.³ In the current study, the same questionnaire was employed and it was administered in English, which was the language of instruction. Part one of the questionnaire featured demographic profiles, part two was a general statement on the participant's status as a student, research scholar, or postgraduate and part three had 14 main statements with several sub statements. Certain statements were purposefully reframed as negative questions to gain a better understanding of the information and prevent prejudice. The following were the prizes for correctly answering the questions:

- A. Correctly answered positive or negative questions +02 points;
- B. Incorrectly answered positive or negative questions +00 point;
- C. If the question had numerous positive or negative responses, each option that was properly ticked received a bonus of one point.

The proportion of successfully answered questions in each group was computed and the results were sorted into pre-determined grades as follows: As excellent - 80-100 %, moderate - 50-80 % and terrible - less than 50 %.³ The data was imported into Ms Excel and analysed with the SPSS 22.0 programme.

Results

Ninety first-year medical students, 84 second-year medical students, 85 pre-final-year medical students, 71 final-year medical students and 60 interns were among the 390 respondents. Less than 5 % of medical students were currently involved in clinical trial study (Figure 1).

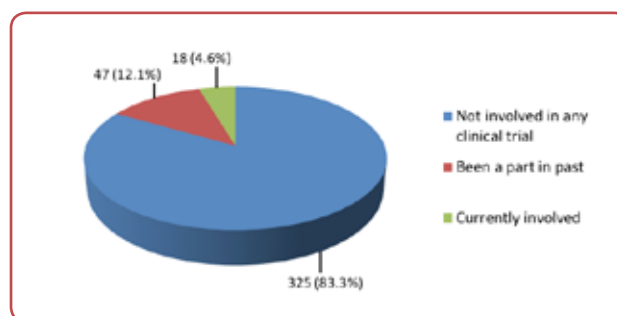


Figure 1: Status of students regarding participation in clinical trials

Clinical trials were familiar to the majority of them (82.1 %). There is a need for clinical trial research, according to 87.2 % of respondents. Clinical trials are a basic requirement for the advance-

Table 1: Questions to determine the level of interest in clinical trials

Questions	Yes N (%)	No N (%)	Don't know N (%)
Awareness about clinical trials	320 (82.1)	52 (13.3)	18 (4.6)
Any need for clinical trial research	340 (87.2)	12 (3.1)	38 (9.7)
Basic requirement for humanity's advancement and wellbeing	302 (77.4)	60 (15.4)	28 (7.2)
Would like to participate as researcher	280 (71.8)	48 (12.3)	62 (15.9)
Believe that clinical trial are unethical, incorrect and purely inhuman	32 (8.2)	308 (79.0)	50 (12.8)
Harmful events are more than the benefits	78 (20.0)	180 (46.2)	132 (33.8)
Clinical trials are a waste of time, money and resources	18 (4.6)	320 (82.1)	52 (13.3)

ment of mankind and health condition, according to 77.4 % of those polled. If any possibilities for clinical trials were available, 71.8 % of the students expressed an interest. Clinical studies are immoral, erroneous and totally inhuman, according to just 8.2 % of participants. Clinical trials are useful to the patient, according to nearly half of students (46.2 %). The vast majority agree that clinical trials are not a waste of time, energy or money.

Table 2: The awareness survey of clinical trials among medical students

Questions	Yes N (%)	No N (%)	Don't know N (%)
Concept of clinical trial	110 (28.2)	225 (57.69)	55 (14.10)
Need of clinical trial	96 (24.61)	220 (56.41)	74 (18.97)
Where can people find out about clinical trial	135 (34.61)	28 (7.17)	227 (58.20)
Participation in clinical trial	50 (12.82)	162 (41.53)	178 (45.64)
Pre-clinical and clinical testing	65 (16.67)	210 (53.84)	115 (29.48)
Institutional review board (IRB)	55 (14.10)	157 (40.25)	178 (45.64)
Role of US FDA in approving new drug	52 (13.33)	205 (52.56)	133 (34.10)
DCGI role	124 (31.79)	102 (26.15)	164 (42.05)
Informed consent	132 (33.84)	172 (44.10)	86 (22.05)
Potential benefits	162 (41.53)	185 (47.43)	43 (11.02)
Potential risks	42 (10.76)	196 (50.25)	152 (38.97)
Leaving a research study	176 (45.12)	132 (33.84)	82 (21.02)
Knowing CRS results	74 (18.97)	140 (35.89)	176 (45.12)
Design of study/placebo/control group	87 (22.30)	196 (50.25)	107 (27.43)
Sponsors	84 (21.53)	198 (50.76)	108 (27.69)
Side effects	87 (22.30)	180 (46.15)	123 (31.53)

US FDA: the United States Food and Drug Administration; DCGI: Drugs Controller General of India;

The average response for the assertions was given by more than half of the survey participants like concept of clinical trial (57.7 %), need of clinical trial (56.4 %), pre-clinical and clinical testing (53.8 %) and role of the United States Food and Drug Administration (US FDA) in approving new drug (52.6 %). Almost half students had average knowledge of potential risks of clinical trials, design of study/placebo/control group and sponsors. Out of total respondents, 58.2 % had poor knowledge of statement of what is the best way for people to learn about clinical trials. The knowledge of Drugs Controller General of India (DCGI) role was good in 31.8 %, average in 26.2 % and poor in 42.0 %.

Discussion

The purpose of this study was to determine the level of awareness about clinical trials among undergraduate medical students and interns. The majority of the questions had an average response. In a studies done by Vittalrao et al³ and Sharma and Jindal⁴ similar outcomes were discovered. This could be due to a lack of organisation in medical education when it comes to student involvement in clinical trials and research. Early engagement in research by undergraduate students will benefit them in making evidence-based decisions for their future practice. Poor understanding and interest could be one of the explanations for students' lack of participation in clinical trials.⁵ Similar outcomes have been recorded in various nations throughout the world. Doctors' participation in clinical research was found to be low in a study conducted in Pakistan.⁶ The other factors include time restrictions and cumbersome paperwork.^{3, 7} So far, research has not been made a requirement in India's undergraduate medical education. Undergraduate medical students were involved in 28 % of publications in one institution in Germany, where research is an integral part of the undergraduate medical curriculum.⁸ According to a survey, 23 % of undergraduate students in Croatia, a European country, took part in research projects.⁹ Sharma and Jindal⁴ found that for the statement about the notion of clinical trials, roughly 20.2 % went into the good group, 61.4 % into the average category and 18.4 % into the bad category in a comparable research of 155 students. The bulk of the remarks on involvement in the clinical research study were in the bad response group (89.2 %), compared to 9.8 % in the excellent response category.⁴ This difference could be because of the involvement of only final year students, while in the present study students from first to final year as well as interns were included. The knowledge of second to final year students could be better due to pharmacology background. According to Goel et al¹⁰ a one-day training session on GCP standards can enable medical practitioners, dentists and nurses to have a better understanding of the concepts and practices of clinical research, hence increasing the credibility of clinical research in the nation.

Due to the low rates of medical professionals participating in clinical trials, greater emphasis should be placed on improving the research experience of medical students and interns in order



to boost their participation in clinical trials.¹¹ According to Chatterjee and Sarkar¹² just 10.9 % of students were aware of the existence of an institutional ethics committee and 42.8 % were unaware of the committee's specific job. Clinical research instruction should be included in the undergraduate pharmacology curriculum, according to Goel et al.¹⁰ The findings in terms of clinical trial idea and understanding are comparable to those of Sharma and Jindal.⁴ Complicated documentation and time restrictions are two of the challenges to starting clinical investigations.⁷ Meenakumari et al.¹³ discovered that 90 % of doctors desired clinical trial training to be included in the undergraduate curriculum. As many as 5 % of medical students may go on to become researchers in the future. As a result, clinical research and medical ethics must be taught to them during their study time. To perform clinical trials, as Thatte and Bavdekar¹⁴ suggests, one must have a solid understanding of basic concepts of clinical research, ethical and regulatory standards and appropriate clinical practices.

The limitations of current study were:

1. Pharmacology subject was not the part of first year medical student's curriculum, so they were less aware about clinical trials.
2. There is a need of multi-centric study for generalisation of the findings as only one medical college was involved in the present study.

Newer developments in medical education, in contrast to factual learning, emphasise the acquisition of skills, knowledge and attitudes. Clinical research is not only an appealing career opportunity, but it is also the cornerstone of evidence-based medicine. As a result, future doctors must be taught how to conduct scientific research in a well-structured, fruitful and ethical manner. Students can improve their clinical research ideas and perspectives by participating in monthly undergraduate clinical research projects, continuing education, workshops and symposiums, as well as organising excursions to contract research organisations (CRO).¹⁵ Students should be encouraged to establish the habit of reading medical journals, since this will aid in the development of the skills required to work as a clinical trial investigator. With all of the aforementioned steps, developing medical community can surely position India at the forefront of the global pharmaceutical business in the hunt for high-quality and cost-effective services to assist drug research.¹⁶

Conclusion

It can be concluded from the findings of this questionnaire survey that undergraduate medical students have a good comprehension of clinical trial basics. Necessary efforts must be taken to increase student knowledge of clinical trials. Students should be encouraged to take part in clinical trials.

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None.

Conflict of interest

None.

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