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ORIGINAL RESEARCH

A Questionnaire-based Study to Assess Understanding Clinical Trials among Undergraduate Medical Students

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ABSTRACT

Background: Clinical trials play an important role in the development of novel drugs. India has become one of the major hubs for clinical trials. There has been a surge in the number of clinical trials. Knowledge regarding clinical trials, clinical research, and its implications, importance, and ethical aspects mustbe incorporated from the level of medical students' under graduation. **Aim:** The study aims to evaluate the knowledge and perceptions of second-year medical undergraduate students regarding clinical trials, specifically focusing on their attitudes toward participation in clinical trials as subjects or investigators. **Methods:** A cross-sectional, questionnaire-based survey was conducted among 166 second-year medical undergraduate students at the Gayatri Vidya Parishad Institute of health care and Medical Technology. Among them,149 consented to participate. The questionnaire consisted of 12 questions to assess the students' knowledge and perceptions.The responses were thoroughly evaluated. **Results:** The findings demonstrated that students were aware of the basic details but lacked significant depth of knowledge regarding the current topic.Despite this, many students expressed an interest in participating in clinical trials as subjects and pursuing careers in the research field as investigators. The awareness of ethical aspects revealed mixed results, and the majority were aware of informed consent. Approximately half of the participants were familiar with the roles of the Institutional Ethics Committee and the Drug Controller General of India, respectively. **Conclusion:** The results highlight significant gaps in knowledge and highlightthe importance of teaching more knowledge at the undergraduate level regarding clinical trials, as well as their importance and safety aspects. This encourages students to gain more awareness and motivates them to pursue careers as investigators and other research-related activities.

Keywords: clinical trials; preclinical toxicology; institutional ethics committee; animal toxicity study; informed consent.

INTRODUCTION

The clinicaldevelopment of chemical entities into a drug is crucialfor the progression of health care.[1] One of the earliest clinical trials on streptomycin for the treatment of pulmonary tuberculosis was undertaken in 1948 by the Medical Research Council. Converting a crude chemical moiety into a drug is tedious, and every new medication is initiated only with volunteers participating in clinical trials.Various processes like manufacturing and sterilization, experimentation for toxic effects on animals, and, finally, clinical trials on humans are involved in the discovery of new drugs. Clinical trials involving drug administration for the first time in humans are essential steps in drug development. Clinical trials are equally important in vaccine development for assessing whether the vaccine successfully stimulates the immune system and produces the required antibody response. Clinical trials are part of evidence-based medicine. They provide a scientific basis for advising and treating patients regarding drug safety, efficacy, dosage requirements, and adverse drug effects.[2]In clinical trials, the drug under investigation is administered in comparison to the standard drug available or a placebo to the study participants, and its superiority to the existing treatment is established. The data obtained from clinical trials are needed to obtain

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approval from regulatory authorities for subsequent drug marketing.[3]

There has been a recent surge in clinical trials, and India is one of the desired destinations for undertaking them owing to various encouraging factors like so and so.[4] The recent pandemic has increased the need to discover and develop new drugs, repurpose old drugs, and develop effective vaccines. In this context, new and ample career opportunities are also welcome for medical students in the field of clinical research. Therefore, there is a need to instil knowledge regarding clinical trials and various ethical aspects involved in clinical research from the undergraduate level.[5]

Basic clinical trial information has been incorporated intothe undergraduate medical curriculum. Based on this background, the present study aimed to assess the level of knowledge and awareness of 2nd-year M.B.B.S medical undergraduates regarding clinical trials and evaluate their perception of participating in clinical trials as a participant or investigator.This is significant because proper knowledge about clinical trials from undergraduates is needed to raise interest among students in seeking a career in research and experimentation.[6] Medical graduates with sufficient knowledge can also create awareness among the public and patients, clarify their false beliefs and apprehensions, and encourage and motivate them to participate as volunteers in clinical research.[2]

MATERIALS AND METHODS

The present questionnaire-based study was conducted among second-year medical undergraduate studentsover a period of one month.The study was conducted after receiving approval from “Institutional Ethics Committee” of the institution (“IEC” No:7576877686). The study subjects were second-year medical undergraduate students of “Gayatri Vidya Parishad Institute of health care and Medical Technology.”Students were given a prevalidated questionnaire containing 12 questions to assess their knowledge and perception of clinical trials. They were asked to fill out the form and submit it duly. The questionnaire consisted of 2 parts: part A and part B. Part A consisted of the demographic details of the student, such as name, age, gender, registration number, and contact number. Part B consisted of questions on the actual topic. Studentspursuing second-year medical degrees during graduation that were willing to participate in the study were included. All students who were not willing to participate were excluded from the study. The questionnaire was distributed among the study participants, and the responses were collected and thoroughlyanalyzed. From the responses provided by the students, their level of knowledge regarding clinical trials and perception of participation were evaluated.The data will be fed into Microsoft Excel and analyzed using SPSS software.

Ethical Approval

"Institutional ethics committee" approval number(“IEC” No:7576877686).

RESULTS

Out of the 166 students, 149 showed willingnessto participate in the study; they duly filled out the form and submitted it. The responses marked by the students were evaluated, and the following results were obtained (Table 1). Out of the total students, male students comprised 40.9% and female students comprised 59.1% of the total second-year students, as depicted in Figure 1.

Questions 1, 2, and 3 aimed to assess the students’ basic knowledge regarding clinical trials and their importance (Figure 2).Questions 4 and 5 were targeted to assess the students’ perceptions and opinions about participating in clinical trials as investigators or participants, as depicted in Figure 3.

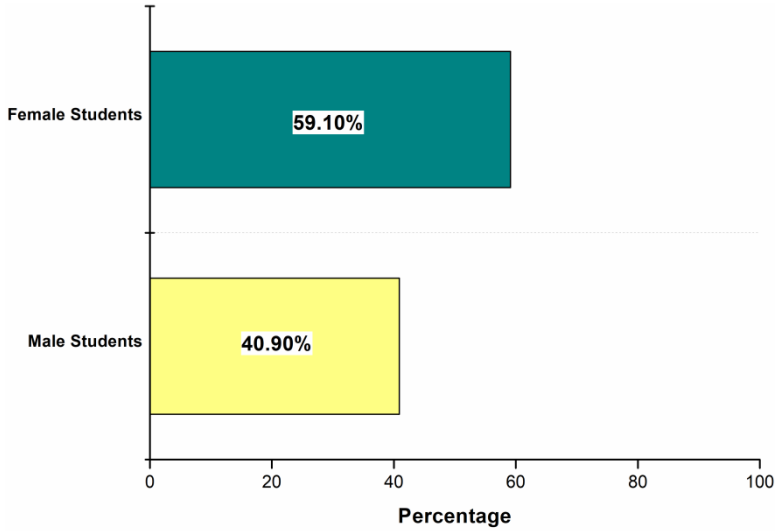

Figure 1: Percentage distribution of students based on gender.

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As shown in Figure 4, Questions 6 and 7 were aimed at assessing the knowledge gap and students'misinterpretations regarding the clinical trial process.Questions 8, 9, 10, 11, and 12 were asked to assessthe student's knowledge regarding terms like Informed consent, Institutional ethics committee, and Drug Control General of India, etc., as depicted in figure 5.

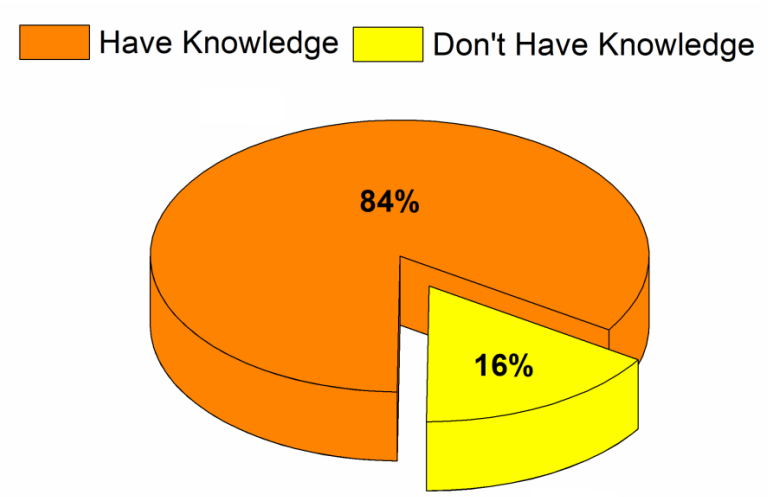

Figure 2: Assessment of students' basic knowledge

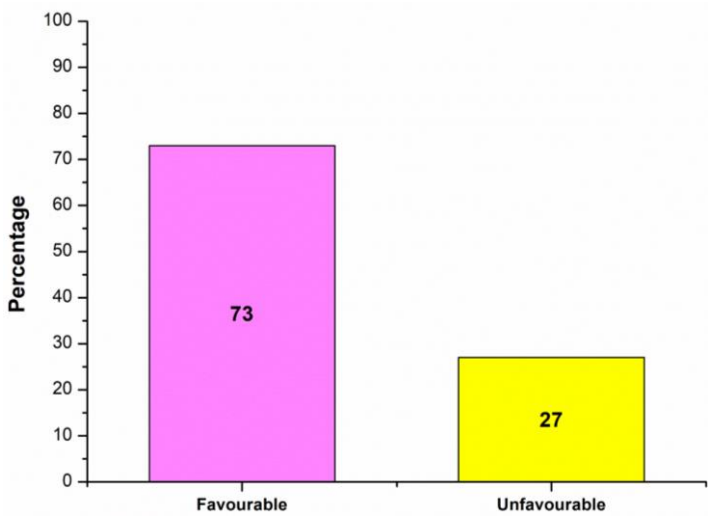

Figure 3: Assessment of student perception and interest in participating in a clinical trial as a subject or investigator

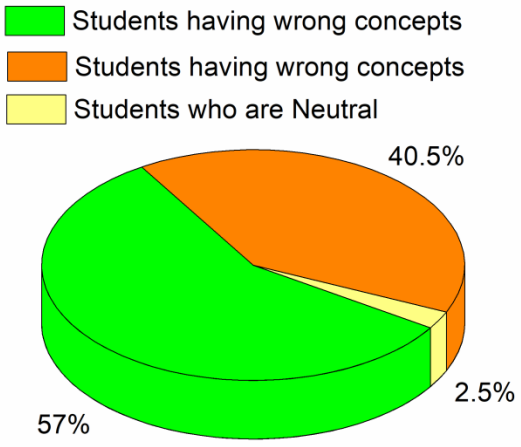

Figure 4: Misinterpretations among students about clinical trials.

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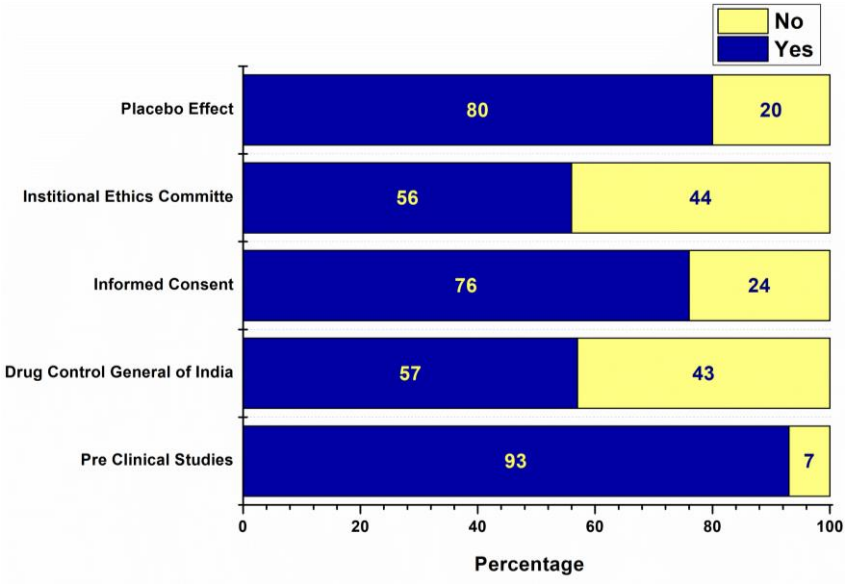

Figure 5: Assessment of more detailed clinical trials

Table 1: Students' responses to the questionnaire.

S. No	Question	Response (yes)	Response (no)	Response (Did not respond)
1.	Do you know what a clinical trial is?	97 percent	3 percent	Nil
2.	Do you know why clinical trials are conducted?	90 percent	3 percent	7 percent
3.	Do you believe clinical trials are necessary?	67 percent	30 percent	Nil
4.	Are you interested in participating in clinical trials?	76 percent	24 percent	Nil
5.	Are you interested in pursuing a clinical trial as an investigator?	70 percent	30 percent	Nil
6.	Do you believe clinical trials are unethical?	75 percent	20 percent	5 percent
7.	Do you believe clinical trials are risky for subjects?	93 percent	7 percent	Nil
8.	Do you have any reasons why preclinical and animal toxicity studies were conducted?	93 percent	7 percent	Nil
9.	Do you know who is "Drug control general of India" is?	57 percent	43 percent	Nil
10.	Are you aware of the term and importance of "Informed consent"?	76 percent	24 percent	Nil
11.	Do you know what institutional ethics committee is?	56 percent	44 percent	Nil
12.	Do you know what a placebo is?	80 percent	20 percent	Nil

DISCUSSION

There has been an increase in the number of clinical and vaccine trials registered and ongoingworldwide.[7] This has become even more significant after the "Covid-19" pandemic, after which the importance of clinical trials was understood worldwide. In addition, India has seen stable growth in the clinical trial industry over the past decade since 2014, with the potential to become a leading clinical trial hub.[8]This has the potential to open many career opportunities in India in the fields of drug discovery and development for pharmacologists and medical professionals.In this context, complete knowledge and awareness regarding clinical trials, animal toxicity studies, drug discovery, and development should be presented to medical students from the undergraduate level. Approximately 90% of medical professionals want clinical trial training to be included in the undergraduate medical curriculum[1].This approach can raise interest in students in the field of pharmacology and encourage them to positively pursue career options in research fields.

The results obtained in this study showed thatmost students were aware of what clinical trials were and

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the reasons for conducting them. Students also played sufficient knowledge about the crucial role they play in drugdevelopment. In addition, students had basic knowledge regarding preclinical animal toxicity studies and the importance of conducting studies on animals before conducting studies on human participants. Even though the majority of students felt that clinical trials were well planned and care regarding safety aspects of the participants will be taken by the investigators and regulatory authorities, 30% of the students still opinedthat clinical trials on human subjects were not safe and they felt could be replaced with alternate procedures not involving humans. This may be due toa lack of complete knowledge regarding clinical trials. In the undergraduate field of pharmacology, information regarding the current topic is provided in the introductory chapters. However, the level of coverage is very basic and inadequate, with much emphasis not placed on its importance. A study by [9] also found that students had insufficient knowledge regarding the current topic.

The majority of students showed willingness and interest to participate in clinical trials, both as participants and investigators, which was a positive factor. However,the reluctance of a small minority of students indicates that they still have apprehensions about clinical trials, indicatingthat gaps in knowledge exist. This highlights the importance of systemic training of medical undergraduates in clinical research.It has been suggested that, if not real-time research, simulation techniques can be used in undergraduate teaching to bridge the gap between knowledge and apprehensions, thereby making students more confident in undertaking research activities in the future.[10]Most students believed that clinical trials were not unethical or inhuman, but the procedures involved could be quite risky for the participating subjects.

The majority of students are aware of theprocedure, and importance. Similarly, they were aware of placebo and its use. However, only 56% and 57% of the students were aware of the terms“Institutional ethics committee” and “Drug Controller General of India”. This highlights the need to include ethics and related aspects in clinical practice and research in the undergraduate curriculum. Many students are applying for ICMR short-term scholarship projects and are even presenting research papers at conferences. Basic training in medical ethics canalso benefit such students. In a study by,[11] the authors and students also felt the need to include ethics in the undergraduate medical curriculum.Students at the undergraduate level should be trained in clinical research. More detailed topics on preclinical and animal toxicity studies, clinical trials and clinical research, ethics, and “Good clinical practice” guidelines should be included in the undergraduate curriculum. Students can also become involved in clinical trials and research activitiesby assisting and observing senior physicians and clinical investigators. Research is often underrated, and much importance is not given in under graduation, which requires attention.[12] Changes can be made in the undergraduate curriculum to make clinical research and trials more familiar for students. This can help students become interested in research activities and develop the skills needed for the future.

CONCLUSION

Based on the findings of this study, we can conclude that the level of knowledge and awareness among undergraduate medical students regarding clinical trials is average. This study highlights substantial gaps in knowledge. This was due to incomplete curricular exposure to preclinical toxicology, informed consent protocols, and ethical governance. It was a high time that students were made more aware ofthe topic. This can be achievedby inculcating more knowledge in the undergraduate curriculum, conferences, and other collaborative workshops and directly exposing students to ongoing clinical research.

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Author Contributions

Akella Krishna Sowmya **conceptualized** and designed the study, supervised the research process, and contributed to data analysis and manuscript preparation.Priyanka Geddam-Conducted the data collection and initial analysis and contributed to manuscript drafting and review.Sunil Kumar Pandey **provided** critical revisions for intellectual content, ensured the accuracy of results, and oversaw the final approval of the manuscript for publication.

Conflicts of interest

The authors declare are no conflicts of interest.

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