

A Study to Assess the Knowledge and Attitude of Clinical trials Among Medical students at a tertiary care institute- A cross-sectional study

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Received: 26-03-2025

Accepted: 17-04-2025

Published: 31-05-2025

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ABSTRACT

Background: Clinical trials are fundamentals to advancing medical sciences, providing evidence for the safety, efficacy, and effectiveness of therapeutic interventions and forms the foundation of evidence-based practice. Medical students, as future healthcare professional, need strong understanding of clinical trial. However, gaps in knowledge and awareness regarding clinical trial still exists, which hinder the student's ability to engage in research effectively. Thus, this study was aimed to assess the knowledge and attitudes toward clinical trials among second year MBBS students in a tertiary care hospital.

Methodology: This cross-sectional study was conducted among second year MBBS students from February to April 2024 at tertiary care teaching hospital in Chengalpattu district. A total of 140 students were participated in this study. Data were collected using a pretested, semi-structured questionnaire pertain to knowledge and attitudes toward clinical trials. Data analysis was performed using SPSS Version 22, and results were presented as frequencies and percentages.

Results: Among the 140 participants, 60.7% of the participants are female with the mean age 20.6 ± 0.95 years. 52.9% correctly identified mandatory documentation for enrolling subjects in clinical trials, and 64.3% correctly identified the purpose of Phase I trials. However, 87.1% were unaware of the pre-clinical phase duration. Overall, 30% of participants had adequate knowledge, and 13.6% had inadequate knowledge. Attitudes were largely positive: 82.1% agreed that clinical trials help assess the risk-benefit ratio of drugs, and 95.7% believed participation in clinical trials enhances drug safety understanding. However, 25.7% perceived clinical trials as resource-intensive, and 33.6% felt they added to academic burdens.

Conclusion: While students demonstrated positive attitudes toward clinical trials, notable knowledge gaps were observed, particularly regarding pre-clinical phases and regulatory aspects. This highlights a critical need for targeted educational interventions within the medical curriculum, especially focusing on early introduction to clinical trial concepts, regulatory requirements, and practical applications.

KEYWORDS: Clinical trial, KAP, undergraduate research.

INTRODUCTION

Clinical trials are fundamentals to advancing medical sciences, providing evidence for the safety, efficacy, and effectiveness of therapeutic interventions. These are essential for the development of new treatments, drugs, and medical devices, and they form the basis for evidence-based practices.¹

Medical students, as future healthcare professionals, need to possess a strong foundational understanding of clinical trials, as they will be involved in patient care, treatment decisions, and potentially even in clinical

research.² Unfortunately, many medical students lack comprehensive education on the importance, process, and ethical considerations of clinical trials. Previous studies have shown that while most students recognize the value of clinical trials, they often have limited knowledge regarding trial methodology, statistical analysis, ethical concerns, and the regulatory frameworks governing clinical research can hinder their ability to make informed decisions about patient participation in trials or even to engage in clinical research themselves.³

However, despite their critical role in healthcare, there is often a significant gap in awareness and understanding of clinical trials, especially among medical students who are the future of the healthcare workforce. Bridging this gap in knowledge and attitudes toward clinical trials is crucial for fostering a more informed medical community that actively participates in and supports clinical research.⁴

In India, clinical trials are particularly significant due to the growing burden of disease and the country's status as a major hub for medical research. With an increasingly diverse population and a unique set of health challenges, the inclusion of Indian participants in clinical trials is essential for generating data that is applicable to the local context.⁵ However, a major challenge in this context is the lack of awareness and understanding of clinical trials among the general population, as well as among medical professionals in training. Medical students of clinical trials influence their future participation in clinical research, both as practitioners and researchers.⁶ Therefore, assessing the knowledge and attitudes of medical students toward clinical trials is critical to addressing this issue. Hence, this study aims to assess the current level of knowledge, awareness, and attitudes toward clinical trials among medical students at a tertiary care hospital.

Objectives:

To assess the knowledge and attitude towards clinical trials among medical students in a tertiary care hospital in Chengalpattu district.

MATERIALS AND METHODS

Study design and setting:

This questionnaire based cross sectional study was carried out among the medical students in a tertiary care hospital in the Chengalpattu district for a period of three months from February to April 2024.

Study participants, sampling technique and sample size:

The study was conducted at Melmaruvathur Adhiparasakthi Institute of Medical Sciences and Research, a tertiary care medical college in Tamil Nadu, India. This institution serves a diverse patient population and offers undergraduate medical education that includes exposure to clinical and research-oriented learning experiences. The second-year MBBS students were included in the study, representing an ideal population for assessing knowledge and attitudes toward clinical trials, as they are at a stage in their education where foundational knowledge of medical research and clinical practices is being established. MBBS students of other years and those not willing to participate were excluded from the study. The sample size was calculated by taking the proportion of knowledge (p) about clinical trial, and absolute precision (d) 8 % at a 95% confidence level.⁷ with 10% non-response rate the sample size was calculated to be 140 using single proportion formula.

Data collection tools and techniques:

We used a pretested, semi-structured questionnaire which consisted of the basic details of the participants, questions related to knowledge about clinical trial and attitude towards the clinical trial. Data were compiled, entered in Microsoft Excel software, and analysed using SPSS Version 22 (SPSS Inc, Chicago IL, USA). All the categorical variables were presented as frequencies and percentages.

Ethical considerations:

Written informed consent was sought from all participants who were enrolled in the study. The scientific and ethical committee approval was obtained from the Institute Research Committee and the Institute Human Ethics Committee respectively. Data safety and confidentiality were maintained at every step of the study.

RESULTS

Demographic Profile of Study Participants:

The study included 140 second-year MBBS students from a tertiary care institute. Among them, 39.3% (n=55) were male, and 60.7% (n=85) were female, with the mean age of 20.6 ± 0.95 years (**Table 1**)

Table 1: Basic details of the study participants (N=140)

Study variables	Frequency	Percentage
Gender		
Male	55	39.3
Female	85	60.7
Age	20.6±0.95	

Knowledge about Clinical Trials

The knowledge of clinical trial concepts among participants was assessed using a set of questionnaires were explained in table 2. 52.9% (n=74) of students correctly identified that which documentation is mandatory for enrolling subjects in clinical research, while 47.1% (n=66) responded incorrectly. Purpose of Phase I Trials was correctly identified by 64.3% (n=90). Maximum number of participants were not aware about Pre-Clinical Phase Duration (87.1%).

Table 2: Knowledge about clinical trial among the study participants:

Knowledge	Correct response	Incorrect response
Document is mandatory to enrol a subject in a clinical research	74 (52.9%)	66 (47.1%)
Primary purpose of a phase I clinical trial?	90 (64.3%)	50 (35.7%)
Which phase focuses on determining the pharmacokinetics and pharmacodynamics of a drug?	57 (40.7%)	83 (59.3%)
What is IND	99 (70.7%)	41 (29.3%)
Largest number of participants involved in which Phase	70 (50%)	70 (50%)
Approval for conducting clinical trials using new drugs in India	81 (57.9%)	59 (42.1%)
Phase I clinical trial is done in	116 (82.9%)	24 (17.1%)
Post-marketing surveillance is done in which phase?	108 (77.1%)	32 (22.9%)
What is ICH-GCP?	60 (42.9%)	80 (57.1%)
A subject's participation in a clinical trial is	94 (67.1%)	46 (32.9%)
Allocation of subjects to treatment groups is by chance	103 (73.6%)	37 (26.4%)
Which of the following is true regarding placebo?	76 (54.3%)	64 (45.7%)
ICH-GCP guidelines are followed in all of the following except	76 (54.3%)	64 (45.7%)
Adverse event occurs in clinical trial should be reported to	85 (60.7%)	55 (39.3%)
What is the duration of the pre-clinical phase?	18 (12.9%)	122 (87.1%)

Knowledge about clinical trial: (Figure 1)

Questions pertaining to knowledge about clinical trial was prepared and scoring was given. Correct response in was given a score of one, whereas the incorrect response was given a score of zero. The scoring ranges

from 0 to 15. Those who score less than five were categorised as having inadequate knowledge, score between 6 to 10 as satisfactory and score more than 10 was considered as adequate knowledge. Based on this 30% of the participants were having adequate knowledge and 13.6% were having inadequate knowledge

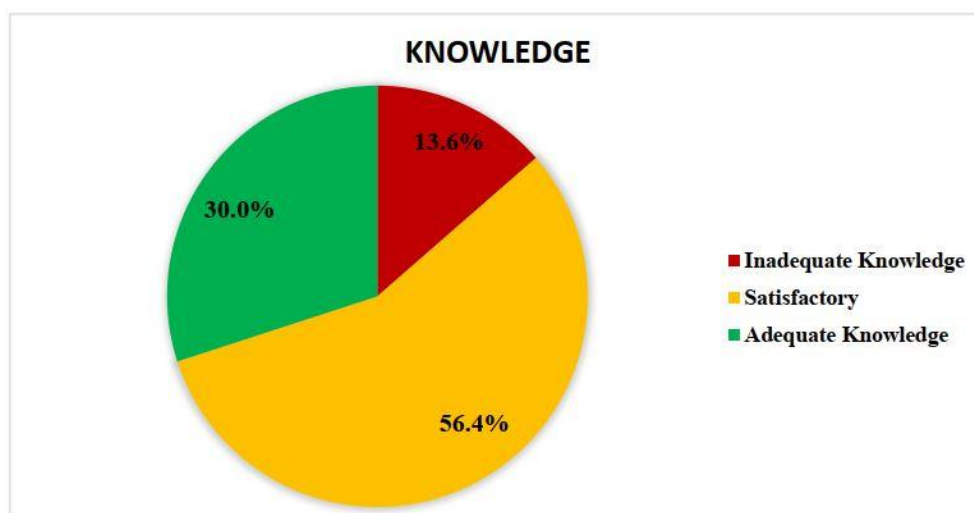


Figure 1: Knowledge categorisation among the study participants:

Table 3: Attitudes towards clinical trial among the study participants

Study variables	Agree	Disagree
Do you think the potential benefit of clinical trial is to deliver basic risk benefit ratio of drugs?	115 (82.1%)	25 (17.9%)
Do you think by participation in clinical trials, doctors obtain a better understanding the safety of drugs?	134 (95.7%)	6 (4.3%)
Do you think conducting clinical trials is just a waste of time, manpower and money?	36 (25.7%)	104 (74.3%)
Do you think understanding clinical trial increases burden on already overworked	47 (33.6%)	93 (66.4%)
Do you think training in ICH-GCP guidelines should be incorporated in UG curriculum?	119 (85%)	21 (15%)

Attitudes toward Clinical Trials

The attitudes of students toward clinical trials were largely positive, as summarized in **Table 3**. A substantial 82.1% (n=115) agreed that clinical trials help to assess the risk-benefit ratio of drugs, while 17.9% (n=25) disagreed. A notable 95.7% (n=134) believed that clinical trial participation provides doctors with a better understanding of drug safety. One fourth of the participants (25.7%) considered clinical trials a waste of time, manpower, and money. 33.6% (n=47) agreed that understanding clinical trials would add to an already heavy academic workload, while 66.4% (n=93) disagreed, suggesting a generally favourable attitude toward integrating clinical trial awareness into their studies.

DISCUSSION

The present study was conducted among the medical students to assess the knowledge and attitude towards clinical trial. The current study was conducted among 140 second-year MBBS students from a tertiary care institute. Among them, 39.3% (n=55) were male, and 60.7% (n=85) were female, with the mean age of 20.6 ± 0.95 years.

This study highlights notable gaps in knowledge and favourable attitudes toward clinical trials among medical students, findings that resonate with similar studies conducted in various parts of India. In the current study, 52.9% of participants correctly identified that documentation is mandatory for enrolling research subjects, and 64.3% understood the primary purpose of Phase I trials. However, awareness was notably low for pre-clinical phase duration (87.1% of students were unaware), similar to findings from other research showing that students frequently struggle with complex concepts, such as the procedural and regulatory aspects of clinical trials.

Studies from Rajasthan and South India report similar results, with 43-57% of students displaying only moderate knowledge of essential clinical trial elements, such as informed consent and institutional ethical review, which are pivotal for conducting ethical and safe clinical trials.⁵ These studies indicate that insufficient emphasis on early clinical research education could contribute to these knowledge gaps, as exposure to research often occurs late in the medical curriculum.⁸

Regarding attitudes, 82.1% of participants in this study agreed on the importance of clinical trials in determining the risk-benefit ratio of drugs, aligning with findings from similar studies where students recognized clinical trials' role in patient safety and drug development.⁷ Furthermore, 95.7% acknowledged that participation in clinical trials enhances understanding of drug safety, reflecting a generally positive attitude towards clinical research. This mirrors findings from research in Madurai, where students appreciated the clinical trial process's value for future clinical practice and research career opportunities.³

Despite these positive perceptions, barriers remain. Around 25.7% of students in this study viewed clinical trials as a waste of resources, and 33.6% felt that learning about clinical trials could add to an already heavy workload, concerns that were similarly noted in research by Johar et al. (2020).⁹ These perceptions suggest that some students may view clinical trials as peripheral rather than integral to their training. Other studies from Maharashtra and South India have suggested that structured curriculum changes, including the integration of clinical trial methodologies and ethical guidelines, could help improve student engagement and knowledge.^{7,10}

Strengths and Limitations:

The study specifically targets second-year MBBS students, an ideal group for understanding baseline clinical trial awareness early in medical education. This focus enhances the relevance of the findings and allows for targeted educational interventions. Findings can directly inform curriculum designers on integrating clinical research concepts within undergraduate medical programs, with an emphasis on areas where knowledge gaps were identified. Even though this study has lot of strengths, it has few limitations, as this research is conducted at a single tertiary care setting, results may not generalize to all medical colleges in India or other regions, limiting its external validity. Since the study relies on self-reported responses, students' knowledge and attitudes may be over- or under-estimated due to social desirability bias or misunderstanding of certain questions.

CONCLUSION

In conclusion, the study confirms that while students show a positive attitude towards clinical trials, their knowledge is often superficial or limited to specific concepts. This highlights a critical need for targeted educational interventions within the medical curriculum, especially focusing on early introduction to clinical trial concepts, regulatory requirements, and practical applications. These findings align with multiple studies across India, underscoring a nationwide need to reform medical education to foster a well-informed future medical workforce capable of contributing to and supporting clinical research.

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Acknowledgement: We acknowledge the cooperation of the participants and the Department of Pharmacology, MAPIMS for their support of the study.

Financial support and sponsorship: Nil.

Conflicts of interest: There are no conflicts of interest.