

A Study to Assess the Knowledge of Medical Students on Clinical Trials in Madurai Medical College

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Abstract: Background: The fundamental tools of modern medicine are clinical research. There is an increasing trend to undertake clinical trials in India in recent years, but its awareness among health care professionals remain far less from satisfactory. Aim: To evaluate general awareness regarding clinical trials among undergraduate medical students. Materials and Methods: A questionnaire based study was conducted among undergraduate medical students of Madurai Medical College. Questionnaire was given to a group of 101 medical students. Descriptive statistics were used for analysis of data. Frequency was expressed in percentage. Results: It was observed that there was good awareness about concept of clinical trials (73.3%) IEC (49.5%) and role of FDA (50.5%). There was average awareness about need of clinical trial (44.6%), participation in clinical trials (53.5%) pre-clinical and clinical testing (47.5%), 61.4% of them were in the poor response category for the statement regarding trial procedures. Conclusion: As in upcoming years clinical research opens a door for huge job opportunities, "Future Investigators" need to be trained in their basic education days about the methodology of the clinical trial. Efforts like conducting CMEs, workshops, symposiums will help us to create a more widespread awareness of clinical research amongst the medical community.

Keywords: Clinical trials, Awareness, Medical students, Questionnaire, Cross-sectional study

1. Introduction

The rapidly growing field of modern medicine is highly benefitted by clinical trials, which serve as an important evidence for safely treating people with a new drug. The pharmaceutical companies in western countries are facing problems due to the strict regulatory authorities, small population leading to slow and expensive subject recruitment [1]. On the other hand clinical trials in developing countries are rapidly exploding due to better availability of ample, diverse group of population, abundant man power, periodical amendments and implementation of rules by regulatory authorities [2][3].

It is estimated that 20-30% of global clinical trial activities are being conducted in developing countries [4]. Thus clinical research in India opens a door for huge job opportunities, and also further emphasizes the need to train our "Future Investigators" in their basic education days about the methodology of clinical trials [5]. So this study was conducted to elucidate the current knowledge of undergraduate medical students on clinical trials, and thereby to help us in designing an effective and targeted training program to develop a skilled workforce for the above purpose.

2. Aim

This study was conducted to evaluate the general awareness regarding clinical trials among the undergraduate medical students.

3. Materials and Methods

Study design and study site

A cross-sectional descriptive questionnaire based study was conducted among undergraduate medical students of Madurai Medical College.

Study Group

Study group consist of 101 medical students comprising of second year, pre-final, final year MBBS students and house surgeons of Madurai Medical College.

Study period: June 2015.

Methodology:

To all participated students, the principal investigator explained the purpose of the study and a written consent was obtained from the participants prior to the commencement of the study. The participants were also informed that their participation was voluntary and that they could withdraw from the interview at any time without consequences. Every effort was made, to be sure that all information collected from the participants, remain confidential. The study was conducted using a self- structured questionnaire in the language English.

Questionnaire:

The questionnaire was divided into seven parts, totally 24 questions.

Part I contained questions on concept of clinical research study.

Part II was based on the need of clinical trial.

Volume 5 Issue 7, July 2016

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Part III was regarding the participation in clinical research study.

Part IV had statements on pre-clinical and clinical testing.

Part V was based on Institutional Ethics Committee and

Part VI was on role of FDA in approving new drugs.

The last part VII had questions on trial procedures.

The answered questions were rewarded as follows:

A. Positive or Negative questions answered correctly - 2 points

B. Positive or Negative questions answered incorrectly -0 point

The percentage of questions which were answered correctly in each part was calculated and this was categorized to pre-fixed grades as follows

75-100% as good, 50-75% as average and <50% as poor.

Data entry and Analysis:

Data entry was done in SPSS version 16 and the results were presented as descriptive statistics and responses were calculated in percentage.

4. Results

Out of 101 medical students, 24 were from second year, 25 were from pre-final year, 27 were final year students and 25 were house surgeons.

In the table 1, the percentages of response obtained for each part of questionnaire were shown.

For the statement regarding the concept of clinical trials around 73.3% fell in the good category, 23.8 % were in the average category and 2.9% were in the poor category.

Regarding the statement for the need of clinical trials, 44.6 % were average responders, 30.7 % were good and 24.7 % were poor responders.

Table 1: Percentage of response for each part of questionnaire

S. no	Statement on	Good category >75 %	Average Category 50- 75 %	Poor category <50%
1	Concept of clinical trial	73.3	23.8	2.9
2	Need of clinical trial	30.7	44.6	24.7
3	Participation in clinical research study	13.9	53.5	32.6
4	Pre-clinical & clinical testing	26.8	47.5	25.7
5	Institutional ethical committee	49.5	22.8	27.7
6	Role of FDA	50.5	28.7	20.8
7	Trial procedures	3.9	34.5	61.6

The statements regarding the participation in the clinical research study showed that a majority 53.5% were in the average response category as compared to 32.6 % in the poor category and 13.9 % in the good category.

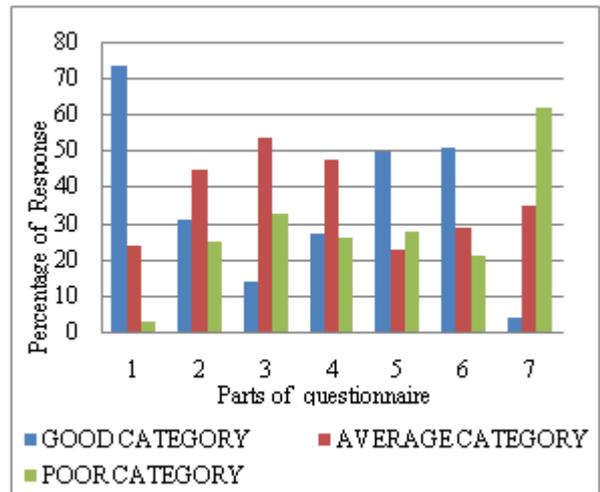


Figure 1: Percentage of Response for each part of questions.

The knowledge regarding preclinical and clinical testing was average in 47.5% students, good in 26.8 % students and poor in 25.7 % students.

Average response by 49.5% students was obtained regarding the Institutional ethics committee, 27.7 % students showed poor response and the rest 22.8 % were good.

The knowledge about role of FDA was good in about 50.5%, average and poor in 28.7% and 20.8 % students respectively.

61.6 % students were not aware about trial procedures in comparison to 38.4 % students who showed average response. Also the awareness was more with the II MBBS and decreased progressively with III years, final years and house surgeons [Table2].

Table 2: Percentage of students answered correctly in each year

Year of study	Percentage
Second year	80.40%
Pre-final year	68.60%
Final year	65.10%
House surgeons	56%

5. Discussion

The present study was aimed to know the level of understanding and awareness about the preliminary aspects of the clinical trials in medical students. From our study it was observed that the students had good knowledge on the basic concepts of clinical trial, however they were less aware about the pre-clinical studies and the trial procedures. This presence of knowledge gaps among students in clinical research has also been observed in similar studies done in other parts of our country [5][6][7].

The newer trends in medical education focus on acquisition of skills, knowledge and attitudes rather than factual learning. Apart from being an attractive career option, clinical research also forms the central pillar of evidence based medicine. Thus it is necessary to train our budding doctors on how to do a carefully structured, fruitful

as well as ethically sound scientific research. Efforts like conducting periodical under graduate clinical research projects, CME, workshops, symposiums and arranging visits to (CRO) contract research organization can help the students to improve their ideas and thoughts on clinical research[8]. Lastly they should also be motivated to cultivate the habit of reading medical journals, which will reflect in their acquisition of skills for becoming a potential „clinical trial investigator“.

Our regulatory system is being polished, laws are being amended to facilitate the entry of global clinical trials and massive concerted efforts are also on to replenish and direct our financial resources towards clinical research[8].

So, in spite of several pitfalls, with all the above initiatives our budding medical community can certainly place India in the top position of global pharmaceutical industry in the search towards high quality and cost effective services to support drug discovery.

6. Conclusion

We conclude from this questionnaire survey that the knowledge for certain basics of clinical trials was average among undergraduate medical students. We must take the necessary steps to make widespread awareness among students about clinical trials. Good motivation should be there for students to undertake clinical research. This will make India a pioneer in global research and development.

7. Future Scope

In the upcoming years more comprehensive studies including a large number of medical and pharmacy students could be conducted to highlight the need for increased emphasis on clinical research in medical curriculum.

8. Acknowledgements

I would like to thank all, who has guided me by extending their knowledge and experience right from the inception to the completion of the work. Last but not least I am thankful to my study participants, without whom, this study would not have been possible.

Funding: No funding sources

Conflict of interest: None declared

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