



**ASSESSMENT OF KNOWLEDGE ABOUT CLINICAL TRIALS IN 3RD SEMESTER
(M.B.B.S) STUDENTS - A QUESTIONNAIRE BASED STUDY IN GOA MEDICAL
COLLEGE, BAMBOLIM**

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ABSTRACT

Background: Clinical trials play a very important role in research. Awareness about the same in medical students is the need of the hour. This study was conducted to assess the knowledge and understanding about clinical trials among 3rd semester MBBS students. **Materials and methods:** This was a cross sectional questionnaire based study, conducted among 3rd semester MBBS students from Goa Medical College after approval from institutional ethics committee (IEC). A pre-validated 18 point questionnaire was given (n=117). Data was analysed using latest version of Microsoft Excel. **Results:** were tabulated as percentages and 117 responses from the students were obtained. The response rate was found to be 78%. The questions regarding general concept about clinical trials obtained 89.14% correct response whereas incorrect response was obtained in 9.73%. Percentage of correct response in ethical category question was 74.77% and incorrect response was 20.73%. Response rate was average in regulatory set of questions with 69.65% giving a correct response and 27.35% an incorrect response. **Conclusion:** Though the overall knowledge about the clinical trial was good, there is further need to encourage and give students opportunity to participate. Early exposure to research would help the students to know about the depth and challenges faced in real life scenarios. Also it will help to build interest in research as they are the future researchers.

KEYWORDS: Clinical trial, questionnaire based study, awareness, 3rd semester.

INTRODUCTION

The science of clinical trials is of para-amount importance in health care as it forms the backbone of medicine. Clinical trials are conducted to approve a new molecule in use, as well as to determine efficacy, safety and comparison with standard treatment available. Approximately 20-30% of the clinical research trials are conducted in developing countries globally.^[1]

Clinical trials are done with a motive of scientific benefit to the human being however they are not free from risks. But most of the trials are being conducted according to Good Clinical Practice (GCP) guidelines ensuring well-being and safety of the participants.^[2]

Modern medicine has become more rational and scientific. It is based on evidence and hence clinical trials and knowledge about it in medical fraternity is important. Most of the teaching medical institutes are involved in conducting trials.^[2] Medical undergraduates are taught in their pharmacology curriculum about the process and importance of clinical trials in brief.

In the present era it is necessary to sensitise young student minds about utmost importance of research in medical field. Also if students are encouraged and allowed to conduct and participate in clinical trials it would be helpful for them to conduct research in future with better participation and knowledge.

The purpose of this study was to assess the knowledge in students about the clinical trials.

MATERIALS AND METHOD

This was questionnaire based study done after institutional ethics committee approval, conducted in Goa Medical College, Bambolim. The questionnaire was administered to 3rd semester M.B.B.S (2nd year) students. Participation in study was voluntary and questionnaire was administered in English.

Questionnaire included total 18 questions. It was divided into three parts: first part included general statement on clinical trials (Q.no 1-7), 2nd part on ethics (Q.no 8-14)

and third part on regulatory statements about clinical trials (Q no.15-18).

The answered questions were rewarded as YES or NO. The percentage of questions which were answered correctly for each questions were calculated. This were graded as follows: 80-100% as good response, 50-80% as average and <50% as poor response.

Data was analysed using latest version of Microsoft Excel.

RESULTS

Out of 150 questionnaires which were distributed, 117 responses from the students were obtained.

Thus in our study response rate was found to be 78%.

The percentages of responses obtained for each question of questionnaire of part 1 is shown in table 1.

Table 1: Question regarding general concept of clinical trial.

	Correct response (%)	Incorrect response (%)	No response
1.Is it necessary to take an approval from IEC before conducting the study?	94.1	3.4	2.5
2.Is informed consent necessary before trial? If yes, then is it actually "informed"?	93.2	6.8	-
3.Are clinical trial conducted only in patients?	98.3	1.7	-
4.Can a volunteer enrolled in a study withdraw from the study before completion of the study?	83.8	16.2	-
5.Should the trial be conducted in animals before human are enrolled in the study?	87.2	10.3	2.5
6.Is phase 1 conducted in healthy volunteers in case of anti-HIV and anti cancer drugs?	76.1	21.4	2.5
7.Can phase 1 trial be conducted in children before it is completed in adults?	92.3	6.8	0.9

For statement regarding general concept about clinical trials in our study correct responses were recorded in 89.2% students, incorrect responses in 9.7% and no response was obtained in 1.1%. (Fig. 1) Response rate was categorised as good.

The percentages of responses obtained for each question of questionnaire of part 2 is shown in table 2.

Table 2: Questionnaire on ethical concept.

	Correct response (%)	Incorrect response (%)	No response (%)
8.Is clinical trial commerce and not science?	90.6	7.7	1.7
9.Do you feel there is need to create awareness among students about clinical trials?	96.6	3.4	-
10.Is placebo a dummy drug?	79.5	19.6	0.9
11.Do volunteers participating in trial receive incentives?	41.9	49.6	8.5
12.Are clinical trials conducted to evaluate the safety and effectiveness of treatment?	96.6	2.6	0.8
13.Do patients/ volunteers taking part in the study, receive any compensation due to any untoward side effects of study?	65.8	25.7	8.5
14.Can participant's details be disclosed during study?	94.9	5.1	-

For statement regarding ethical concept about clinical trials in our study correct responses were recorded in 74.8% students, incorrect responses in 20.7% and no response was obtained in 4.5%. (Fig. 1) Response rate was categorised as average.

The percentages of responses obtained for each question of questionnaire of part 3 is shown in table 3.

Table 3: Questionnaire on regulatory science of clinical trials.

	Correct response (%)	Incorrect response (%)	No response (%)
15. Do you know who is DCGI? If yes, what is the full form of DCGI	28.2	71.8	-
16. Is permission given for marketing the drug after phase 3 trial?	70.1	27.3	2.6
17. Are GCP guidelines to be followed while conducting a clinical trial?	88.9	2.6	8.5
18. Should all trials be conducted according to autonomy, beneficence, non-maleficence and justice?	91.5	7.7	0.8

For statement regarding regulatory concept about clinical trials in our study correct responses were recorded in 69.7% students, incorrect responses in 27.3% and no

response was obtained in 3%. (Fig. 1) Response rate was categorised as average.

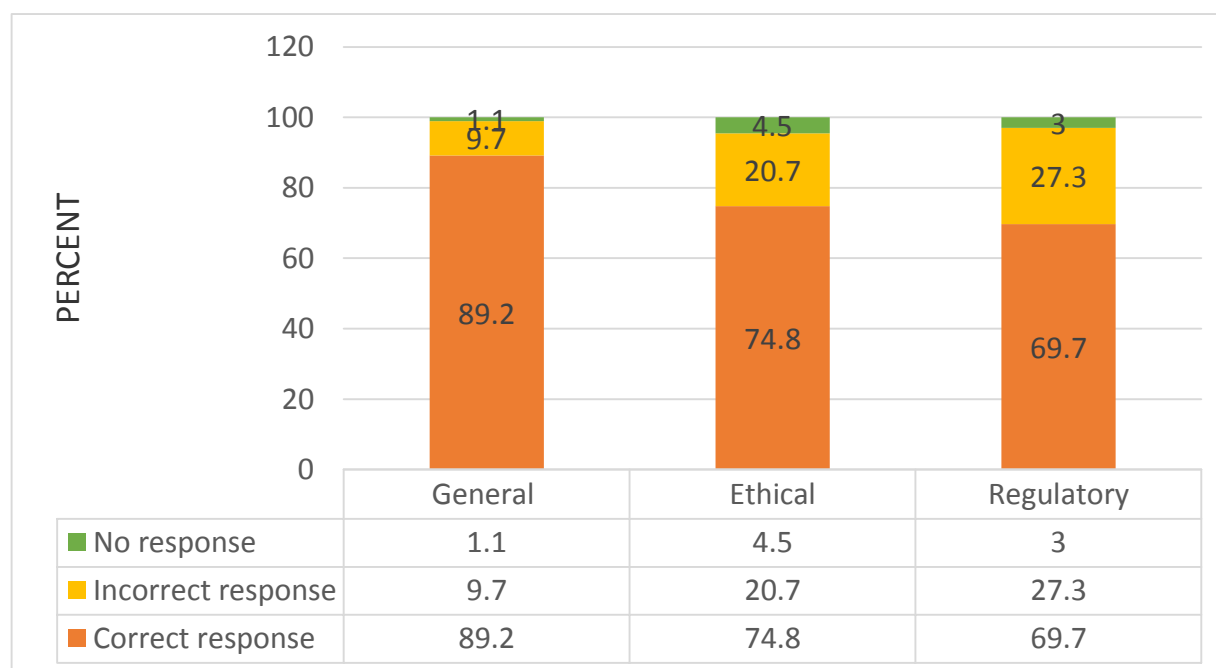


Fig 1: Percentage of response rate of each part of questionnaire.

DISCUSSION

The present study was conducted in order to understand the knowledge about clinical trials in MBBS students. In our study it was observed that students have good knowledge about basic concepts on clinical trials. However response was graded as average with respect to ethical and regulatory statements on clinical trials.

This is in contrast to studies done earlier in India like Sharma et al^[3] and Kanna RS et al^[4] where overall response was found to be low.

In study done by Vittalrao et al^[2], response was found to be average.

Research has not been compulsory part of MBBS curriculum and thus practical knowledge in students is still lacking.

Research activities should be introduced as part of MBBS curriculum to make students aware of importance of research projects and ethics and awaken their interest in same to continue ongoing research in future.

Reason for lack of participation in clinical trial activities could be

- not compulsory part of curriculum,
- cumbersome paperwork which can consume more time.
- lack of motivation, also poor knowledge about it etc.

Student wing should be established in each institute and opportunity given to all the students who are interested to take up research projects and activities. ICMR has been funding short term studentship program since 1979 to encourage students among medical undergraduates. This can be used for starting up medical research lab and activities in institute.

Medical curriculum should be recapitulated with special emphasis on research activities and provide platform to encourage constant student participation. Newer concepts in medical fields relies on acquiring skills, knowledge rather than factual learning. Student should be motivated to attend CMEs, workshops symposiums and read medical research journals to understand practical approach toward trials and research work being conducted.^[5] Clinical research serves as a part of evidence based medicine thus can serve as an attractive career option.

Thus knowledge about how to conduct trials and about medical ethics can be incorporated among young budding doctors during their undergraduate days as they are the ones who are future investigators of the country.

The study conducted showed that the knowledge about the clinical trial was good. But it was conducted on a smaller scale in few number of students. So the data cannot be generalised. Also students should be encouraged there and opportunities can be provided for them to participate. Students should be given early exposure to research. This will help them to know about the depth and challenges faced in real life scenarios. Also it will built interest in research as they are the future researchers.

LIMITATION

- The study was conducted on a small scale.
- Only limited number of questions were asked.

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