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Research Article

Evaluation of knowledge regarding good clinical practice among faculties at a tertiary care teaching hospital

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ABSTRACT

Background: This study was aimed to assess the knowledge regarding basic aspects of conduct of clinical trial and associated regulatory as well as ethical issues before and after and educational intervention in form of a workshop on Good Clinical Practice (GCP).
Methods: One day workshop on "Good Clinical Practice" was planned which included important ethical and regulatory issues regarding clinical research. Various resource persons from industry and academia were chosen to address the workshop. Total 60 participants were enrolled for this one day workshop. Pre-workshop questionnaire of 15 questions were distributed before the actual topic started. Each participant had to fill the questionnaire form and return it within 15 minutes. Again at the end of workshop, post-workshop questionnaire containing the same questions were distributed and the participants were asked to fill the form. Sequence of questions was changed in post workshop questionnaire. Comparison between answers in pre and post workshop questionnaire was done. The primary outcome was knowledge, which was evaluated using the Wilcoxon signed rank test.
Results: In Pre workshop, out of 60, total 28 (46.66%) participants had answered all 15 questions, while 30 (50%) participants had skipped to answer one question "Define GCP." 2 out of 6 (3.33%) participants had not answered 4 and 5 questions out of 15, respectively. Total 45 out of 60 (75%) participants in post workshop answered all questions. All 15 (100%) questions were answered correctly in post workshop as compared to 11 (73.3%) questions in pre workshop. So, in post-workshop, there were significant ($P < 0.005$) gains in knowledge regarding all good clinical practice questions.
Conclusions: Good clinical practice knowledge improved markedly with a targeted education intervention in form of workshop. However, changes in behaviour and attitude were not studied by this questionnaire based study.

Keywords: Clinical trial, Ethics, Questionnaires, Humans, Workshop

INTRODUCTION

We know that clinical research is necessary to establish the safety and effectiveness of specific health, medical products and practices. Much of what is known today about the efficacy and safety of specific drugs has come from randomized and controlled clinical trials that are designed to answer important scientific questions. We can rely on clinical research only if it is conducted according to principles and standards collectively referred to as "Good Clinical Research Practice" (GCP).[1] The responsibility for GCP is shared by various parties involved in clinical research, i.e. investigators, sponsors, regulatory authorities, contract research organizations (CROs), ethics committees and research subjects.[2,3] Many of us are associated with clinical research either as investigator and/or ethics committee member. As a part of the team, we are expected to have sufficient understanding of the scientific, ethical and administrative aspect of biomedical research on human subjects including an awareness of the regulation and guidelines of conducting clinical trials.[4] Moreover, in order to

standardize and regulate clinical research, a lot of advances have been taking place with respect to role and responsibilities of various stakeholders of clinical research especially by the national regulatory bodies. Hence, conducting a successful clinical trial not only requires a strong basic knowledge, but also updating them on regular basis.

This study was aimed to assess the knowledge regarding basic aspects of conduct of clinical trial and associated regulatory as well as ethical issues. For that, a workshop was organized with the aim to educate our faculty members/ethics committee members. Before and after study design was used to evaluate the prior understanding and how much knowledge they gained after the workshop.

METHODS

Present study was a questionnaire based cross-sectional study, carried out in November 2014. There was no control group, as before and after study design was used. The primary intervention was a one day workshop (9 AM to 6 PM) on "Good Clinical Practice (GCP)" at GMERS medical college, Sola-Ahmedabad held on 18th November 2014. Total 60 participants were enrolled for workshop and all included for the study.

The workshop included lectures, practical work and small group tasks focussed around six topics including core areas of GCP: Good Clinical Practice, clinical trial, regulations in India and schedule Y; role and responsibilities of investigator; informed consent process; role and responsibilities of ethics committee; safety reporting and compensation in clinical trial.

Resource persons from academia as well contract research organizations having enormous knowledge and vast experience of GCP and clinical trials had covered all the key points and ethical issues.

A written questionnaire was used to measure knowledge, the primary outcome. The questionnaire consists of 15 questions regarding the basic knowledge about conduct of clinical trial, its regulatory and ethical issues. Out of 15, 14 questions were of multiple choice questions, whereas only one question was about understanding the concept of good clinical practice.

Pre workshop questionnaire was given before starting of first session and all the participants were instructed to fill it within 15 minutes. The questionnaires were collected from all the participants and then only the workshop was started. After completion of all the sessions, post workshop questionnaires were distributed and allowed to fill it within 15 minutes. Pre workshop and post workshop questionnaires consisted same questions but the sequence of those was changed.

After collection, all the questionnaires were checked for completeness and assessed for correctness. Analysis was done to compare the correctness of the answered questions before and after the workshop. Data was analysed using the Wilcoxon signed rank test with help of GraphPad InStat version 3.1 (GraphPad Software, USA).

RESULTS

Table 1 shows the basic educational and professional characteristics of the participants. Majority of them (41 out of 60) were the clinicians likely to become principal investigator in the clinical trials. Only 9 out of 60 participants had not participated in any clinical research, while 16 participants had done more than one research activity.

Table 1: Demographic details of the participants (n=60).

Characteristic			n (%)
Educational qualification	M.B.B.S.		7 (11.6)
	M.D./M.S.		51 (85)
	Diploma		2 (3.3)
Time since graduation	<5 years		23 (38.3)
	5-10 years		24 (40)
	>10 years		13 (21.6)
Primary work role	Clinical		41 (68.3)
	Academic		19 (31.6)
Participation in any clinical research	Yes	Only PG thesis	35 (58.3)
		Others	16 (26.6)
	No		9 (15)

Descriptive statistics, including means and percentages, were used to compare the outcomes. Initially all the questionnaires were checked for their completeness. In Pre workshop, out of 60, total 28 (46.66%) participants had answered all 15 questions, while 30 (50%) participants had skipped to answer one question "Define GCP". 2 out of 6 (3.33%) participants had not answered 4 and 5 questions out of 15, respectively.

Total 45 out of 60 (75%) participants in post workshop answered all questions (28.34% more than pre workshop).

For the correctness of the knowledge, Wilcoxon matched pairs signed ranks test was used to evaluate change in objective knowledge. Differences in percentage and confidence intervals were calculated. Highest increase in knowledge (54% improvement) was seen with questions involving Declaration of Helsinki and ICH. Majority of participants knew about "IRB", "Sponsor", "SAE" etc. 10 out 15 questions were answered correctly by all the participants (100%) in post workshop evaluation. Even in post workshop, only 22% participants were able to answer "Define GCP" (Table 2).

Table 2: Difference of % between before and after GCP workshop in answering questions correctly.

Question	Correctness in answering Question (%)		Difference
	Pre workshop	Post workshop	
What is a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's SOPs, GCP, and the applicable regulatory requirements?	74.35	100	25.65
An SAE (Serious Adverse Event) is any untoward medical occurrence that at any does:	84.87	100	15.13
A clinical trial must have IRB/IEC approval before it can begin?	82.30	100	17.7
According to the principles of ICH GCP what is the most important consideration when conducting a clinical trial?	69.23	100	30.77
What does ICH stand for?	20.51	74.19	53.68
Which document created in 1964 forms the basis of ethical considerations in clinical research?	46.15	100	53.85
Prior to subject's participation in the trial, the _____should be signed and personally dates by the subject or by the subject's LAR.	77.17	100	22.83
According to ICH GCP the investigator "should be qualified by....."?	79.48	100	20.52
The person responsible for the conduct of the clinical trial at a trial site	74.35	100	25.65
Sponsor responsibilities include	74.35	100	25.65
In your words, define GCP?	7.69	22.58	14.89
According to ICH GCP where would you expect to find a section entitled "Summary of Data and Guidance for the Investigator"	23.07	45.16	22.09
What does IRB Stand for?	66.66	70.96	4.3
What does ICH GCP state about the investigator or trial staff persuading subjects to take part in a trial? "Neither the investigator, nor the trial staff, should ..... a subject to participate or to continue to participate in a trial"	30.76	48.38	17.62
An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.	76.92	100	23.08

Each value is expressed in percentage. P value is <0.001 which is highly significant using Wilcoxon matched-pairs signed-ranks test.

DISCUSSION

Because of limited sample size and short duration during various phases of clinical trials, it is of utmost importance that clinical trial process and data must conform to rigorous standards to ensure that decisions are based on data of highest quality and integrity. Good Clinical Practice is the process to define and ensure ethical and scientific quality standards for clinical research and it is consistent with the principles enunciated in Declaration of Helsinki and International Conference of Harmonization (ICH). Medical faculties are likely to become principal investigator in different areas of clinical research or member of institutional ethics committee. Due to larger number of patient load as well as other responsibilities of medical education, knowledge regarding these regulatory guidelines always remains in grey area. So one day workshop was conducted to educate medical faculties on the core areas of GCP. Knowledge was assessed by pre workshop and post workshop questionnaire.

Similar kind of study was undertaken by Sorensen GB & Kristensen AB involving Danish physicians.[5] They used questionnaire consists of 22 questions as compared to our 15 questions. Also, there was involvement of 1000 physicians of different hospitals. In present study, only 60 participants were included. In our study, only 22.58% participants correctly answered the explanatory question "Define GCP" as compared to other Multiple Choice type of Questions (MCQ), while in that study all questions were of MCQ type.

In similar study conducted by Annie McCluskey and Meryl Lovarini in School of Exercise and Health Sciences, University of Western Sydney[6] intervention was a two days' workshop on "evidence based medicine", as compared to present study. Inclusion of 8 month follow up questionnaire was the key feature assessing retention of the knowledge over longer period, which was lacking in our study. Another study conducted by Nisha Jha, Omi Bajracharya and P. Ravi Shankar in Nepal showed that after educational invention, there was

significant improvement in knowledge, attitude and practice regarding medicines.[7]

CONCLUSIONS

Good clinical practice knowledge improved markedly with a targeted educational intervention in form of workshop. However, changes in behaviour and attitude were not studied by this questionnaire based study.

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