Original Article

Effectiveness of workshop training in basic principles of Good Clinical Practice among the Medical teachers - A cross sectional study

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ABSTRACT

Background: Good Clinical Practice (GCP) is an international quality standard for conducting trials that involve participation of human subjects. Good Clinical Practice guidelines are provide the human rights protection, assurance of the safety and well being of subject participating in clinical trials of the newly developed compound. The objective of this study was to show the effectiveness of workshop training in basic principles of Good Clinical Practice among the Medical teachers of Government Medical College, Bhavnagar and will learn the practical application of GCP regulations for critical components of the clinical research Process.

Objective: The main objective of this study was to show the effectiveness of workshop training in basic principles of Good Clinical Practice among the Medical teachers

Methods: A total 125 medical teachers of Government Medical College attached with Sir Takhtsinhji Hospital, a tertiary care hospital, Bhavnagar, Gujarat professionals were participated in Good Clinical Practice training workshop. The study was included total twenty questioners based on the most widely accepted international document forming the base for ICH Harmonised Tripartite Guideline for GCP (ICH-GCP E6), which defines in detail the responsibilities and obligations of parties engaged in clinical research. They were submitted given questioners with answers before and after the workshop training. The data was Mean and SD calculated using SPSS software.

Results: The total twenty questions were analyzed and compare with the standard key of this. Pre training test score of Question no. 2, 5, 7, 16 was 19(15%), 35 (28%), 21 (17%), 14 (11%) and post training score was 70(88%), 95(76%), 64(51%), 75(60%) respectively. This number as well as percentage could show more improvement in knowledge regarding basic principle of Good Clinical Practice. In our study results shown that there was improve overall knowledge after the given Good Clinical practice training.

Conclusion - Training workshop with interactive sessions among the participants after some lectures followed by Multiple Choice Questions test not only improved but also update the participations knowledge regarding subject.

KEY WORDS: Good Clinical Practice (GCP), International Conference on Harmonisation (ICH), Workshop

Key Massage:

Knowledge about Guidelines of GCP is required for each health care professional those directly involved in research practice. Guidelines not only serve the interests of the parties actively involved in the research process, but protect the rights and safety of subjects, including patients, and ensure that the investigations are directed to the advancement of public health objectives.

Introduction

The history of Good Clinical Practice (GCP) statute traces back to one of the oldest enduring traditions in the history of medicine: The Hippocratic Oath.

Good clinical Practice is defined as "A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected". The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. [1]

It was developed in response to some serious cases of fraud and abuse of patients rights.[2] Since GCP rules were first made mandatory by the United States (US) Food and Drug Administration, they have been widely implemented by regulatory authorities in Member County of the World Health Organization including India.[3]

In the Clinical Trials (new drug use in human) Regulations 2004, [4] health care professional who recruit patients, they are required the knowledge and understanding of ICH-GCP guidelines. Rules for GCP also provide "a resource for editors to determine the acceptability of reported research for publication". [5] Many investigators and their research staff or associates are not fully educated about the principles and practical application of GCP rules.[6] Training in GCP teaches these scientists how to improve the standard of clinical trials research[7]. Gennery stated that training is one of the most critical areas in the process of GCP [8]. It is also important for medical students, residents, fellows, physicians, graduate students in health or other related disciplines, and personnel from the pharmaceutical industry and regulatory authorities [9].

Objective:

The main objective of this study was to show the effectiveness of workshop training in basic principles of Good Clinical Practice among the Medical teachers, Govt. Medical College attached with Sir Takhtsinhji Hospital, a tertiary care hospital, Bhavnagar, Gujarat Bhavnagar.

Materials and Methods

A Cross Sectional study carried out at Government Medical College attached with Sir Takhtsinhji Hospital, Bhavnagar in Medical teachers involving Clinical Research. We had conducted one day training workshop on basic principle of Good Clinical Practice and total 125 participants were registered in the training. The training includes traditional lectures using presentation Slides, video, discussion and a number of interactive exercises such as group discussions based on relevant case studies. We have checked the current knowledge of basic principles of Good Clinical Practice by pre-training questioners (validated and pre designed) and also checked the post training questioners after completion of workshop training to assess their knowledge. The questionnaire consisted of twenty multiple-choice questions type on basic principles of Good Clinical Practice in clinical research methodology based on the 1990 European GCP guidelines particularly ICH-GCP (E6) Guideline. Their questioners having four choices and one correct answer in each question. The questioners were tested knowledge in the following areas: basic principle of Good Clinical Practice, roles and responsibilities of parties involving research, ethics, and data management.

Results:

The table show pre training and post training score in the number as well as percentages of correct answer of twenty questioners. The most of post training questions score was increased as compare with pre training questioners test. Before training, score of Question no. 2, 5, 7, 16 was 19(15%), 35 (28%), 21 (17%), 14 (11%) and after training score was 70(88%), 95(76%), 64(51%), 75(60%) respectively. The other questioners score was also improve but the number as well as percentage not more than above questioners score. Our study results shows that with such type of

education like training workshop under Continue Medical Education (CME) will definitely improve and update the knowledge regarding topic.

Table: Pre training and Post training score of Participants

Sr. No	Questions	Pre test Score	Post test Score
1	Three basic ethical principles are derived from	71 (57)	105 (84)
2	GCP is part of following ICH topic	19 (15)	70 (88)
3	Reporting the progress of the trial at site is the responsibility of	71 (57)	98 (78)
4	Ethics submission and approval is the responsibility of	63 (50)	68 (54)
5	Corrections in the CRF is the responsibility of	35 (28)	95 (76)
6	Investigational Medicinal Products can be shipped to site	76 (61)	85(68)
7	IMP accountability is the responsibility of	21 (17)	64 (51)
8	Which of the following are included in informed consent	81 (65)	109 (87)
9	What does ICH GCP state about the investigator or trial staff persuading subjects to take part in a trial?	41 (33)	61 (49)
10	According to ICH GCP any trial related duty and function that is transferred to and assumed by a CRO should be what?	24 (19)	44 (35)
11	Of what is this part of the ICH GCP definition: "A unique identifier assigned by the investigator to each trial subject to protect the subject's identity"	61 (49)	63 (50)
12	According to ICH GCP which of the following is the odd one out in terms of where it/they should be filed?	16 (13)	38 (30)
13	Complete this statement from ICH GCP: neither the investigator, nor the trial staff, should XXX or unduly influence a subject to participate or to continue to participate in a trial.	40 (32)	95 (76)
14	Which of the following is NOT an ICH GCP requirement for clinical trial sites?	55 (44)	58 (46)
15	Which of the following is most true regarding the ICH GCP requirements for an investigator?	41 (33)	58 (46)
16	Which of the following is not an SAE	14 (11)	75 (60)
17	Investigator shall report all SAE to sponsor within 24 hours and to the Ethics Committee within	55 (44)	68 (54)
18	What completes the following statement from ICH GCP Section 4.9 regarding Essential Documents?	50 (40)	75 (60)
19	All laboratory abnormalities that are greater than three times the upper or lower limit -of- normal are reported as serious adverse events in all clinical trials	33 (26)	70(56)
20	To be classified as an Adverse Drug Reaction, a causal relationship between a medicinal product and an unintended response to that product must be at least a reasonable possibility.	44 (35)	93(74)

Discussion

This study is provides quantitative and qualitative evidence that training improves and update the knowledge of medical professional. This is the simplest method for checking and updates the knowledge by education. Further, we are see how much improve the knowledge by administer set of objectively structured questions before and after the training and to analyze the difference.

Halder and co-workers assessed the effectiveness of training in infant feeding practices amongst 34 community level health workers in West Bengal[10].They held multiple training sessions for the participants also called 'Influencers'. They conducted an assessment before the commencement of training and repeated assessments after every training session. They concluded that their training improved the knowledge of the participants and that repeat sessions were very helpful. In our study, significant differences were found in post training score.

In another Indian study, knowledge on Vitamin A deficiency was imparted to 95 Anganwadi workers in Haryana through lectures, demonstration and discussion. The participants were divided into two groups with the first group being shown colored film slides in addition to the other methods while the second group was not shown the slides. Pre and post test showed significant increase in knowledge in those groups that show the slides. The authors conclude that use of audiovisual aid increases the transfer of knowledge [11]. In our study, power point slide presentations were used for the delivery of lectures.

Similar methods of assessing and update the knowledge by organizing such type training workshop and teaching sessions have been used to be helpful for general practitioners [12]; asthma patients [13]; school teachers [14], and parents [15].

This study was found that there is a need for a training program in basic principle of Good Clinical Practice in clinical research not only improve but also update and increased the knowledge of clinical research in medical professional. Following the training workshop, there was significant improvement in knowledge of the participants regarding different aspects of Good Clinical Practice ($P = 0.005$ by paired t test).

Since clinical research of different disciplines has much more common. The training program should begin before participation of the researcher in a clinical trial. All people involved in clinical trials, particularly those who have direct contact with subjects, need to understand fully their responsibilities as defined by rules of GCP. They should understand how to obtain informed consent correctly, complete case record forms accurately, and monitor and record any adverse events properly. This should result in improved staff performance which will increase the safety of the study subjects and contribute to quality data.

This study identified a strongly recommended for such type of training program related to basic principle of Good Clinic Practice in clinical research among medical professional.

The limitations of this study were the small number of participants, only one day training workshop, checked immediate recall of knowledge.

The evaluation results show the training workshop stimulated empowering knowledge among medical professional who participating in clinical research. The training workshop is anticipated to generate significant improvements and update in knowledge, attitudes, behaviors related to research participation among individuals who have less knowledge in the past (pre test score) with and knowledge of the research process and research ethics.

Conclusion

The studies have shown using interactive sessions with slide presentation and followed by multiple choice questions test not only improved but also update participants knowledge regarding topic. Results of this study could be used to guide the development and implementation of continuing medical education program for medical professional to enhance knowledge about basic principle of Good Clinical Practice in clinical research.

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