ORIGINAL RESEARCH PAPER

Pharmacology

Volume - 7 | Issue - 3 | March - 2017 | ISSN - 2249-555X | IF : 4.894 | IC Value : 79.96

Awareness of clinical trial among resident doctors - Survey at a tertiary care teaching hospital in Gujarat

KEYWORDS

Awareness, Survey, Clinical trial, Resident doctors

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ABSTRACT

Background: There is an increasing trend to undertake clinical trials in India, but its awareness among the resident doctors remain far from satisfactory. Resident doctors are not specially trained on clinical trials (CTs) in their postgraduate curriculum.

Aim: This questionnaire survey was designed to assess the level of knowledge, perceived understanding and awareness regarding basic aspects of conduct of clinical trial and associated regulatory as well as ethical issues among resident doctors.

Materials and Methods: A cross sectional, descriptive, questionnaire based survey was conducted among resident doctors of Civil Hospital, Ahmedabad. Study duration: 3 months

Results: Out of the 420 residents approached, 217 returned the completed questionnaire (response rate 51.7%). 4% residents had participated in CT as sub investigator. Majority (70%) were unaware about which CTs taking place at their institute. Majority (67%) were undecided about future participation in CTs. Overall good level of knowledge about different phases, types and sites of CTs was observed. Information of documentary requirement of CTs by regulatory bodies was lacking. Knowledge regarding research informed consent and financial compensation (69%) was average. Knowledge regarding role of ethics committee (41%), investigator responsibilities (40%), sponsor responsibilities (60%), safety reporting (30%) and drug regulatory bodies (39%) was low.

Conclusion: The study has revealed specific areas of deficient knowledge, which might be emphasized while designing training on CT methodology.

Introduction:

World Health Organisation (WHO) definition for clinical trial is 'any research study that prospectively assigns human respondents or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes[1]. New drug get marketing authorization only after it has undergone a clinical trial. There is increasing difficulty for the testing of new drugs in developed countries due to strict regulations, elaborate safety and compensation requirements and small populations. Opportunities in India are increasing as it has large population, high Incidence and epidemiology of disease, treatment Naïve patients, large Hospital Infrastructure and English speaking doctors[2]. As the multinational drug companies in the United States and Western Europe look eastwards to outsource research and clinical trial activities, India is to take the fair share in the clinical outsourcing business. Investigator plays an important role for clinical trial. Investigators at study sites, monitor clinical trials and collect and analyse trial data, report adverse events and write and publish clinical-study reports. Since investigators are often specialists in the disease area being studied, today's postgraduate residents are tomorrow's potential investigator. Many reviews show that India has highly skilled clinicians but lacks skilled investigators[3]. There is a shortage of trained manpower. All research involving human respondents is strictly governed by the principles of good clinical practice (GCP). A large majority of potential investigators lack the fundamental knowledge of regulatory, ethical and GCP guidelines to conduct the clinical trial. Research methodology and clinical trials is part of postgraduate course curriculum of Pharmacology but it is not given much importance in other clinical subjects. Lack of formal training in research methodology and bioethics during graduate and postgraduate courses is a definite handicap for the investigators.

Many clinical trials are conducted in various department of Civil Hospital, B J medical college in Gujarat. Resident doctors assist in documentation and patient check up with investigator physician. Since resident doctors may be tomorrow's investigator it was thought worthwhile to assess their knowledge regarding clinical trials. Clinical trial can be a one of the treatment options for some of the patients when existing treatment failed and can give an access to potentially new research treatments.

Objective

The study aims at assessing the knowledge of clinical trial methodology among postgraduate resident doctors.

Methods

Study design

This was a cross-sectional survey conducted from November to October 2015 at Civil Hospital, B J Medical College, Ahmedabad.

Study respondents

We approached 420 post graduate residents from various clinical departments. The residents were explained about the aims and objective of the study. The pre-validated questionnaire was distributed after seeking verbal consent from residents. Those who were not willing to participate or did not return the questionnaire within the given time were excluded from the study.

Data collection tool

We developed a pre-tested, structured questionnaire based on our study objectives. It was subjected to a thorough peer review by our faculty members. The questionnaire consisted of 16 multiple choice questions. The questionnaire consisted of three parts. The first part collected demographic information of the residents: Age, gender, academic year, and speciality. The second part assessed the residents experience and interest in clinical trial. The third part assessed the resident's fundamental knowledge about clinical trial.

Statistics

Information from the returned questionnaires was entered into Microsoft excel worksheet. The data was analysed using appropriate tests.

Results:

Out of 420 postgraduate resident doctors approached, 217 returned completed questionnaires (response rate 51.7 %). Table 1 shows the basic demography of the respondents. Highest response was from medicine department (20.7%) The Male/ female ratio was 1.35: 1. The mean age of study respondents was 27.45 ±1.74 Years.

Table 2 shows the experience, awareness of available trial at institute and respondents interest in future participation in clinical trial. Most of respondents (96%) had not participated in clinical trials. Those who have participated (4%) had worked as sub investigators.

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Table 1 Demographic characteristics of respondents (N=217)

	Number (n)	Percentage (%)
Medicine	45	20.7
Ophthalmology	33	15.2
Paediatrics	22	10.1
Orthopaedics	22	10.1
Dermatology	20	9.2
General Surgery	19	8.7
TB Chest	15	6.9
Gynaecology	15	6.9
Psychiatry	15	6.9
ENT	11	5
Total	217	100

Table 2 Experience/Interest of respondents about clinical trial (N=217)

	Number	Percentage
Experience in clinical trial	10	4.60
Awareness about clinical trial taking place at institute		
Aware	50	23
Not aware	167	77
Interest in clinical trial		
Interested	72	33
Not interested	26	12
Undecided	119	55

When asked about different phases of trial, most respondents did not know about phase 0 trial (84%), while good level of knowledge (79%) was observed in remaining phases of trials. In a question regarding types of trials, most of the residents were aware about Treatment trial (70%), Preventive trial (50%) and Diagnostic trial (50%),while poor knowledge is seen about Screening trial (35%) and quality of life trial (28%). The belief regarding place of conducting clinical trials was in government hospital (92%), private hospital (69%) and contract research organisation (46%). Few respondents (39.2%) had correct knowledge about regulation of clinical trials in India. Knowledge about document requirement of animal data (69%), approval from Directorate Controller General of India (DCGI) (83%) was good while knowledge about document requirement of Institutional ethics committee (IEC) approval (32%) and Clinical Trials Registry- India (CTRI) registration (31%) was lacking.

Question regarding different parameters evaluated during phase III trials, correct response observed for comparisons with standard drug, efficacy and safety was 87%, 74%, 46% respectively. In a question regarding informed consent 152 (70%) respondents gave correct response. Very few (7%) respondents had correct knowledge about reporting of serious adverse event (SAE) to all the three authorities i.e., DCGI, sponsor and IEC. Majority of respondents were of opinion of reporting of SAE to DCGI (73%) while very few responses were noted to sponsor (23%) and IEC (16%).

As shown in Figure 1, very few respondents were aware of role of ethics committee (41%). Only 62% respondents were aware about financial compensation for study related injury or death. Average knowledge about sponsor responsibility (60%) and principal investigator (46%) responsibility was observed.

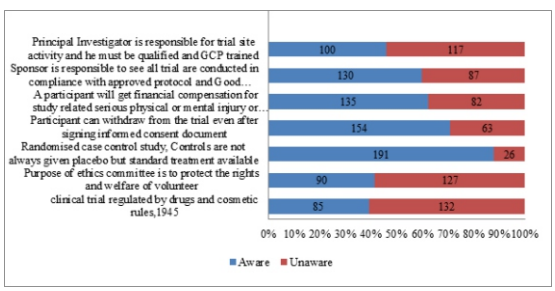

Figure1: Knowledge of resident doctor's regarding clinical trial

Most common source for obtaining information about clinical trials was textbook (67.7%) followed by seminar or lectures (23%), Journals on clinical trial (12%) and other sources (12%). 70 (32%) respondents had no opportunity to access information on clinical trial (Figure 2).

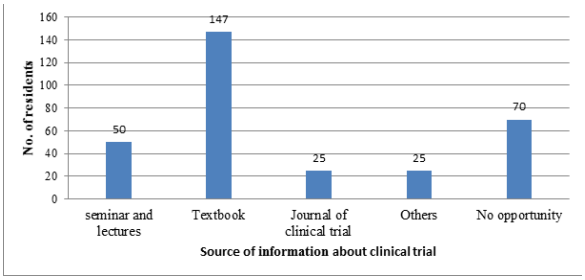

Figure 2: Source of information about clinical trial

Discussion:

Clinical studies are the cornerstone of medical development, and clinical trials are the most important way of evaluating innovative medical treatments. We approached 420 resident doctors working at a tertiary care, teaching hospital out of which 217 returned the completed questionnaire (response rate 51.7%). The busy schedule of resident doctors could be a reason that half of them did not return their filled questionnaire. Many residents had not decided about their future participation in clinical trial. Possible reasons could be lack of specific knowledge or skills required for conduct of clinical trial, workload constraints, lack of qualified mentor or different aim in profession. Undergraduate curriculum included teaching on basics of clinical trial hence good level of knowledge was seen about phases of trial or types of trial. In present study, lack of knowledge about phase 0 was observed. It is understandable as it is a recent change in trial methodology. Most residents were aware about treatment trial, preventative trial, and diagnostic trial while very few were aware about screening and quality of life trials types. This response pattern could be due to large number of the published trial are of treatment, preventative and diagnostic trial while comparatively less number of screening and quality of life trials are published. Majority of respondents believe that clinical trial takes place at government hospital followed by private hospital and contract research organisation. A possible reason for such a result may be attributed to the all respondents belonging to government research institute. All people involved in clinical trials, particularly those who have direct contact with patients, 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. An informed consent from each participant is a mandatory prerequisite for a clinical trial. Majority of respondents answered correctly when asked about the fundamental principles of obtaining a valid informed consent. In a study by Tempte J(1994), it was observed that there was marked disparity between level of knowledge and actual practice with regards to informed consent[4].

For conducting clinical trials in India there are several laws, regulations and guidelines to plan and monitor trials in a fair and ethical way[5,6]. Few respondents (39.17%) had correct knowledge about regulation of clinical trials in India under Drugs and Cosmetics Act 1940 and Rules 1945; schedule Y and Indian GCP guidelines. Information about documentary requirement of animal data (69%), Directorate Controller General of India (DCGI) approval (83%) was good while knowledge about requirement of documents IEC approval (32%) and CTRI registration (31%) was lacking. Good level of knowledge was observed about different parameters studied during clinical trials. Very poor knowledge about reporting of serious adverse event (SAE) was observed. Similar observation was seen in study in Gujarat state where reason cited was lack of sensitization and lack of knowledge of Pharmacovigilance and ADR among postgraduate doctors[7]. Investigators are in charge of actually

Volume - 7 | Issue - 3 | March - 2017 | ISSN - 2249-555X | IF : 4.894 | IC Value : 79.96

conducting the study and are accountable for conduct of the study at a site by personally supervising the investigations.

As shown in figure 1, very few respondents were aware of role of ethics committee (41%). This was surprising as resident doctors were required to take permission from institutional ethics committee for their postgraduate dissertation Good Clinical Practices (GCP) is a shared responsibility amongst sponsors, investigators, regulators and ethics committees. Average knowledge about sponsor responsibility (60%) and principal investigator (46%) responsibility was seen. Only 62% respondents were aware about financial compensation for study related injury or death. This result clearly demonstrates resident doctor's poor knowledge about clinical trials research methodology. The result is in agreement with study in Ahmedabad by Kamal et al where low awareness of clinical research amongst final year medical students and physicians was found[8].

Several limitations should be considered in the present study. First, the present study was conducted in single tertiary care teaching center. Although almost Indian hospitals has limited infrastructure for clinical research and Resident doctors are mainly engaged in clinical practice in India, the survey does not wholly reflect the awareness of resident doctors in India. The health system and clinical research infrastructure vary among various hospitals in India; generalisability of the results in the present study in national settings should be examined in future. Second, the questionnaire was designed originally to survey the present awareness and experiences of resident doctors. Since awareness of resident doctors may vary depending on their past experience. A possibility of recall bias cannot be eliminated.

Conclusions

In spite of various limitations, we found that resident doctors have only limited knowledge of clinical research. To improve physician awareness of the available trial at institute, there is need to develop user-friendly, transparent, up-to-date, and easily accessible centralised registry. There is clearly a need to examine why some resident doctors are reluctant to take part in clinical trial. There is need of experienced mentors to provide guidance on the clinical research process focusing mainly on role of ethics committee, Investigator responsibilities, protocol adherence, data management, informed consent and adverse event reporting. There is clear need of exposure to Clinical Research Center (CRC) by arranging study visits. Such efforts can lead to practical aspect about trial conduct in real life scenario. Training programme on clinical trial would help to improve their knowledge.

Clinical significance

This will help the institutional officials to develop focused research training by arranging conferences, symposium, and workshops on clinical trial research methodology which would further help the resident doctors to conduct and guide research in a more appropriate manner.

Acknowledgement

We are very thankful to all resident doctors who participated in this study.

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