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Original Article

Motivating factors for recruitment of children in clinical trials

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Abstract

Background: Studies have shown that recruitment is the main limiting factor for conducting clinical trials in children. Reports from the Western nations revealed that parents enroll their children in clinical trials mainly due to altruistic reasons. Hence, the present study has been envisaged to evaluate the factors motivating parents to allow their children to participate in clinical trials from a developing country. ***Methods:*** The present study was conducted in a tertiary care university private hospital amongst the parents whose children had participated in any of the three clinical trials that were conducted between 2003 and 2007 in the same centre. A pre-validated structured questionnaire consisting of both open- and close- ended items was used for the study after obtaining permission from the author of the questionnaire. The completed questionnaire was then analyzed using descriptive statistics. ***Results:*** : Of the 136 parents identified from the earlier trials, of which 44 parents participated in the current study. Of these, 36 (81.8%) parents remembered the process of consenting for their child and reported that they had enough time to make their decision and 38 (86.4%) parents felt that they had received sufficient information in the clinical trial they had participated. The parents provided multiple reasons for enrolling their children in the research study. The most commonly stated reason was "contribution to science" (41, 93.2%), followed by 'benefit for their child' (40, 91%). A total of 40 (91%) participants stated that they felt obliged to participate in the trial. Only two (4.5%) of the participants mentioned that they felt any disadvantages in participating in the clinical trial. Only 24 (54.5%) parents had reported that they would take part in a similar study if invited in the future. ***Conclusion***: In conclusion, it appears that majority of the parents in India enroll their children in trials for the reason that are similar to those in developed countries. However, studies on a larger sample and in trials of a varied nature are needed to confirm our findings.

Key words: Vulnerable population, children, pediatric clinical trials.

Introduction

Historically, the pharmaceutical industries, regulators and society have been averse to the idea of exposing children to new drugs by enrolling them in clinical trials. However, this attitude has led to rampant off-label use [1,2] whereby children are exposed to drugs whose safety, efficacy and dosage schedule has not yet been determined. This has led to a re-think on the part of scientists and regulators who are now, in fact, insisting on conducting clinical trials in children for drugs intended for use in them. This has resulted in an enormous increase in the number of pediatric trials. [3]

It is believed that parents are generally reluctant to enroll their wards in clinical trials and this is associated with a slow recruitment rate. [4-8] Some studies have tried to determine the reasons for why parents enroll their children in clinical trials; however, most of these studies have been carried out in developed countries. [9-11] Despite many challenges in conducting clinical trials in India, [12] it remains a preferred country for clinical research and it is likely that more pediatric studies would be carried out here. Given the differences in income, educational level, and literacy rates between India and the developed world, the reasons why parents would want to enroll their children in trials could be different here and hence the present study was undertaken.

Material and Methods

This study was conducted in a tertiary care university private hospital between January 2014 and July

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2014 after obtaining the approval from the institutional ethics committee. The study population included parents whose children had participated in any of the three clinical trials that were conducted between 2003 and 2007 in the same centre. All the three clinical trials were non-therapeutic (vaccine trials) and were conducted on healthy children. Parents were enrolled in the study after obtaining informed consent.

A pre-validated structured questionnaire [13] consisting of both open- and close- ended items was used for the study after obtaining permission from the author of the questionnaire. The questionnaire was also translated into Hindi and administered to the parents in the language they best understood after validation. The completed questionnaire was then analyzed using descriptive statistics.

Results

Of the 136 parents identified from the earlier clinical trials that had been completed, 64 parents could not be contacted. Amongst those contacted (n=72/136), 28 (39%) declined to participate, leading to a final count of 44 participants. Of these, 36 (81.8%) parents remembered the process of consenting for their child and reported that they had enough time to make their decision and 38 (86.4%) parents felt that they had received sufficient information in the clinical trial they had participated. The parents provided multiple reasons for enrolling their children in the research study. The most commonly stated reason was "contribution to science" (41, 93.2%), followed by 'benefit for their child' (40, 91%). 24 (54.5%) parents mentioned that one of the factors that influenced their decision to allow their child to participate in the trial was the doctor asking or requesting them to participate. A total of 40 (91%) participants stated that they felt obliged to participate in the trial. Similarly all the parents felt there was an advantage in taking part in the study and 10 (22.7%) of them mentioned that they had obtained extra care to their child. Only two (4.5%) of the participants mentioned that they felt any disadvantages in participating in the clinical trial. Only 24 (54.5%) parents had reported that they would take part in a similar study if invited in the future.

Discussion

The present study has demonstrated that parents enroll their children for multiple reasons. Most of the parents felt obligated to participate. Although in the present study where all the previous clinical trials were non therapeutic vaccine studies, this notion is not likely to have significant consequences, but can be erroneous in a therapeutic trial where the risk benefit is yet unknown.

Although differences in terms of socio-economic and cultural factors exist between us and the developed countries, where the previous studies were carried out, the findings of the present study is similar to them. Langley et al [14] and Sammons et al [8] reported that, most of the parents enrolled their child for altruistic reasons such as desire to contribute to clinical science, and desire to help others. Rothmier et al reported [10] financial benefits as one of the motivating factors for parents to enroll their child. None of the participants in our study attributed their decision to financial benefits.

Our study had a few limitations. Respondents of the three clinical trials had enrolled their children in studies that were conducted 7-11 years back and thus the possibility of recall bias cannot be ruled out. All the enrolled children were healthy and thus the risk benefit assessment that occurs in a therapeutic trial was not applicable here. Selection bias cannot be ruled out as only one-third of the parents had participated in the present study.

In conclusion, it appears that majority of the parents in India enroll their children in trials for the reason that are similar to those in developed countries. However, studies on a larger sample and in trials of a varied nature are needed to confirm our findings.

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