Participation in clinical trials 2013 in Tokushima National Hospital

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Introduction

Clinical trials involving new drugs are commonly classified into four phases. The drug-development process will normally proceed through all four phases over many years. Each phase has a different purpose and helps scientists answer a different question:

In 2007, a "Five-year plan to activate a new clinical trial" for the purpose of strengthening the enforcement system of clinical trial / clinical studies was presented. It was said that examination was necessary of the methods of transmission of the results of clinical trials / clinical studies and disclosure. To support the investigational promotion for subjects, the provision of burden reduction costs for subjects and reporting for the subjects recruitment were started. The environment surrounding clinical trials is regulated well now.

In the Tokushima National Hospital, a diagnosis / the treatment of patients with neurodegenerative disease was digested primarily. As for the clinical trial, phase two, phase three, or phase 4 was performed.

However, it is not necessarily easy to acquire agreement for investigational participation even if environmental maintenance to be treated with clinical trial advances. We report the data of clinical trials and the data of the consciousness in subjects with the experience of participating in clinical trials / clinical studies.

Results and Discussion

Table 1 shows the list of number of clinical trials for patients with neuromuscular disorders in Tokushima National Hospital. The subjects were 25 people from among the outpatients of Tokushima National Hospital who had participated in a trial in the past. The age of the subjects was 46-82 years old (average of 66.6 years old). There were 16 men, and 9 women. A question paper was mailed to the subjects with a reply envelope. The subjects who agreed to the study returned the investigation paper. We decided to investigate the change of consciousness for the clinical trial. The study period was from June 1, 2010 to March 31, 2012. The statistical analysis used a chi-square test.

Before the clinical trial participation, there were 16 people who had not heard the term "clinical trial". None of the subjects understood the meaning of "the clinical trial". None of the people thought that clinical trials were not necessary by a social life. The number of patients who thought that clinical trials were necessary was 11 before their participation, and 23 after participation. There were 14 patients who had not thought about clinical trials before their participation.

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Table 1 Summary of clinical trials for patients with neuromuscular disorders

Drug	Phase	Target Disease	Enrollment
A	2	AD	2
B	2	PD	21
C	2/3	ALS	12
D	3	ALS	4
E	4	CIDP	60
F	4	PM/DM	1
G	4	PD	10
H	4	AD	5
I	4	AD	10
J	4	PD	1
K	4	PD	10

AD, Alzheimer's disease; PD, Parkinson's disease; ALS, amyotrophic lateral sclerosis; CIDP, Chronic inflammatory demyelinating polyneuropathy; PM, polymyositis; DM, dermatomyositis

This number significantly decreased to 2 after participation ($P < 0.05$).

The significance of clinical trials was compared by participation before and after. However, patients who were regarded as "development of the highest therapy" with participation before and after was most common. There was not a significant difference by participation before and after ($p<0.05$). The patients who had " expectations about receiving new medicine" when participating in a trial were most common, with 19 people. Those who felt that explanation of the investigational participation was easy to understand numbered nine people. About half of the subjects had intended to cancel a clinical trial on the way. The reasons included the lack of efficacy (7 patients, 54%) and an adverse event (6 patients, 46%). There were no subjects who felt uneasiness about medical staff. There were 13 people who thought that it was good to participate in a trial. The patients who thought that it was not good numbered 12 people. Thirteen patients felt that clinical trial becomes imminent and we may participate if there is an opportunity to be for clinical trial as follows. There were three patients who did not want to participate in a clinical trial.

The patients were proved to have barely understood what was involved in a clinical trial until they participated in one. In other words, when recruiting future subjects, it is important to explain the investigational meaning and the details of the investigation clearly.

The investigational need in the social life got possible to understand only after they participated in a trial. Most subjects felt clinical trials were for "the development of better therapy". Similarly, the thing that was regarded as important on the occasion of trial participation, "the expectation to a new medicine" is big. The subjects were almost able to understand the explanation of the medical staff. If they found it hard to understand the explanation, they seem to have participated in trials based on their trust in medical staff. As for the image after clinical trial participation at our hospital, an affirmative opinion was quite partial. It is very important that consciousness for the clinical trial of subjects is analyzed in investigational promotion. Consciousness investigation has been accomplished so far in various kinds of institutions [1,2]. These results are intended to be utilized for service and publicity work for subjects taking part in clinical trials in the future.

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