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承認済み医薬品の臨床試験における女性参加の状況

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Fact-finding Survey of Female Participation in Clinical Trials in Japan

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Summary

Sex-related differences in the pharmacokinetics, efficacy, and side effects of many drugs have been reported. Thus, with the aim of collecting data that would be useful to promote the safe and proper use of drugs, we surveyed and analyzed female participation in clinical trials in Japan. We checked the summaries of application documents reported from April 2001 to September 2012 for pharmaceutical products, as published on the website of the Pharmaceuticals and Medical Devices Agency. The ratio of female participation in clinical trials was higher among phase II (97.1%) and III trial (98.3%), but lower in phase I or a clinical pharmacology trials (60.0%). Moreover, even in studies where the number of female participants was sufficient, data were not necessarily evaluated separately for males and females. This may be the reason why there were rather few reported sex-related differences among trial results, although such differences were sometimes observed in pharmacokinetics, efficacy, or side effects of drugs. Taken together, the data suggest that possible sex-related differences in pharmacokinetics, occurrence of side effects and drug sensitivity are not well-considered during many clinical trials. Greater efforts to recruit female participants for clinical trials at each stage are needed to ensure the development of safe and efficacious drugs.

Key words

Clinical trial, Sex differences, Pharmacokinetics, Phase I, II and III, Clinical pharmacology trial