

Clinical Evaluation of Functional Foods

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Use of functional foods for health promotion and disease prevention has increased over the years. The reasons for consuming functional foods are to decrease the risk of certain diseases and age-related changes along with enhancing physical performance. Unfortunately, some functional foods lack sufficient scientific evidences to support health effects at the present. Korea Food & Drug Administration is recently preparing to authorize the health claims of functional foods. The validation process should include two parts. One part consists of sufficient scientific evidences from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles. The other consists of significant scientific agreement among professionals qualified by scientific training and experience to evaluate such claims.

Because studies that are uncontrolled and nonrandomized are subject to bias, researches related to randomized controlled trials are recommended to evaluate the efficacy and safety of the functional foods. And the researches should be evaluated on the aspect of patient recruitment, trial design, and statistical analysis. Because of the heterogenous nature of the functional foods being investigated and the ambiguity of the outcome measures used, the clinical trials should be reviewed qualitatively as well as quantitatively.

Most papers on functional foods are susceptible to various methodologic shortcomings.

Those papers may have several methodologic limitations including a lack of double-blinding, insufficient sample size, insufficient statistical power, short treatment period, and poorly defined diagnosis.

Basically the principles of clinical trials on functional foods are similar to those on drugs, but we have to take into consideration that some of the characteristics of functional foods are different from those of drugs. For example, there are few expected differences between true

functional food and placebo, therefore in some cases adequate biomarkers may be needed in clinical trials of functional foods. In terms of safety, the risk of adverse reaction to functional foods may be less than that of drugs, but we need to evaluate the safety of the functional foods both in clinical as well as in preclinical stage because functional foods may be used much longer than drugs in general.

In conclusion, clinical evaluation of functional foods should be based on objective and scientific evidences, and these evidences have to be derived from well-designed studies which were performed under popularly accepted scientific process and principles. Comprehensive evaluation of different data from in vitro tests, animal studies, clinical trials, and epidemiologic studies is needed.

Since functional foods can be categorized as both food and drugs, collaboration among professionals in pharmacy, medicine, and nutrition is required and development of evaluation tools for functional foods are essential.