

治験参加を希望する患者の意思の尊重

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Respect for willingness of patients to participate in clinical trials

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Abstract

Introduction : Patients who participate in clinical trials have to satisfy eligible criteria; inclusion and exclusion criteria. Most eligible criteria are set up medical reasons; however, some criteria, such as sex, age, body weight, and infection test, are sometimes set up without medical reason.

Objective : We investigated whether the eligible criteria were adequately set up from the point of view of respect for willingness of patients to participate in clinical trials.

Findings : Eligible criteria are described in clinical trial protocols, which are published by the Pharmaceuticals and Medical Devices Agency (PMDA) as new-drug application (NDA).

Sex: Male patients were excluded in a phase III clinical trial of 7 medicines for osteoporosis.

Age: Because of an inadequate upper limit on age in inclusion criteria, eligible overage patients could not participate in six phase III clinical trials of 19 medicines for type 2 diabetes.

Body weight: Unnecessary criteria for body weight or Body Mass Index were observed in some clinical trials.

Infection test: Unnecessary tests were conducted in a few clinical trials.

Conclusion : In the planning of clinical trials, the above issues should be considered from an ethical point of view. Finally, further analyses should be conducted using information on not only NDA but also on the clinical trials before the NDA, which can be accessed from the trial registry website.

Key words

Ethics, clinical trial, eligible criteria, inclusion criteria, exclusion criteria, sex, upper limit of age, body weight, body mass index, infection test

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