博士後期課程

令和 2年度
武蔵野大学大学院　薬科学研究科　薬科学専攻 博士後期課程　入学試験問題 （9月22日）
［ 英語 ］ 次の文章を読み、各問に答えよ。

①Geriatric patients can respond differently from younger patients to drug therapy in a number of ways and such differences can be greater in patients 75 years and older:

a) The geriatric population has (②)-related physiological changes that can affect the pharmacokinetics of the drug, and the pharmacodynamic response to the drug, both of which can influence the drug-response and the dose response relationship.

b) Geriatric patients are more prone to adverse effects since they often have co-morbidities and are taking concomitant therapies that could interact with the investigational drug. The adverse effects can be more severe, or less tolerated, and have more serious consequences than in the non-geriatric population.

With the increasing size of the geriatric population (including patients 75 and older) and in view of the recent advances in pharmacokinetics and pharmacodynamics since the ICH E7 guideline was established in 1993, the importance of geriatric data (from the entire spectrum of the geriatric patient population) in a drug evaluation program has increased.

Not all potential differences in pharmacokinetics, pharmacodynamics, disease-drug, drug-drug interactions and clinical response that can occur in the geriatric population can be predicted from non-geriatric populations, as ③the geriatric patients are far more likely to have multiple illnesses and to be receiving multiple drugs. Therefore, to assess the benefit/risk balance of a drug that will be used in the geriatric population, these patients should be appropriately represented in clinical trials.

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The pharmacokinetics in geriatric patients (over the entire spectrum of the geriatric patient population) should be evaluated to identify (②)-related differences that are not explained by other factors such as reduced renal function or weight differences. ④The potential influence of impaired renal/hepatic function as well as potential drug interactions is often assessed in studies with non-geriatric subjects.

Population pharmacokinetic analysis could provide the requested data if a sufficient number of patients in different age ranges (including patients >65 and >75 years) are included in the clinical trials. The applicability of population pharmacokinetics is dependent on several factors, e.g. the representation of the target population, the pharmacokinetics of the drug, dosing regimens and analytical requirements.

A specific pharmacokinetic study comparing non-geriatric and geriatric subjects in the same study

(matched for relevant covariates, e.g. weight, sex) could achieve the same goals.

More details on the pharmacokinetic approach (population pharmacokinetics, the appropriate design of a specific pharmacokinetic study) and assessment of drug-drug interactions can be discussed with the regulatory agencies.

（ICH-E7 Studies in Support of Special Populations: Geriatrics -Questions & Answers- より引用）

＜英単語＞
population pharmacokinetic analysis: 母集団薬物動態解析、covariate: 共変量

問 1　下線部①を和訳しなさい。

問 2　高齢者の薬物治療における留意点を、問題文の内容に基づいて列挙しなさい（日本語で）。

問 3　2 か所の（　②　）に共通に入る最も適当な一語を、問題文から抜き出して記載しなさい。

問 4　下線部③を和訳しなさい。また、ほぼ同じ意味の記述を、問題文から抜き出して記載しなさい（英語で）。

問 5　下線部④を和訳しなさい。

問 6　臨床試験における母集団薬物動態解析の適用可否について、問題文の内容に基づいて述べなさい（日本語で）。