(科学・産業：薬学文書翻訳サンプル)

文書種類：新薬臨床試験報告書概要

(日本語)

「健常成人男子を対象としたXYZ単回投与臨床試験報告書」

治験薬剤コード：XYZ

要約：
健常成人男子32名を対象にXYZを0.5、1.0、2.0、3.0mg/kg（各群実薬6例、プラセボ2例）を単回点滴静脈内注入し、安全容量範囲の推定及び薬物動態の検討を行った。

安全性：
副作用は、10例40件（1.0mg/kg群で2例23件、2.0mg/kg群で2例5件、3.0mg/kg群で6例12件）認められた。臨床症状の発現によるものは3例18件（1.0mg/kg群で1例14件、3.0mg/kg群で2例4件）で、唾液腺炎及び感冒に伴う症状であった。前者は、潜在感染がXYZ投与後顕在化した可能性が疑われた。臨床検査値の異常変動は10例20件（1.0mg/kg群で2例8件、2.0mg/kg群で3例5件、3.0mg/kg群で5例7件）で、感冒や唾液腺炎に伴う異常変動以外には、1.0mg/kg群で尿中白血球増加、2.0mg/kg及び3.0mg/kg群で一過性の白血球及び好中球の減少とリンパ球（比率）増加が認められた。

薬物動態：
XYZの薬物動態には非線形性が認められた。また、尿中への排泄は認められなかった。

結論：
本治験で確認された副作用から、XYZ投与時には感染抵抗性が減弱する可能性が示されたが、重篤なものは認められなかった。臨床検査値の中で、XYZの薬理作用を示す容量依存的な変動が認められたが、その変動に依存する臨床的に問題となる所見は認められなかった。

(English)

Report on the Clinical Study of Single-Dose Administration of XYZ to Healthy Male Adults

Code for test substance: XYZ

Summary:
The test substance was administered to a total of 32 healthy male adults by single intravenous drip in different doses (0.5 mg/kg, 1.0 mg/kg, 2.0 mg/kg, and 3.0 mg/kg). In each dose group, XYZ was administered to six subjects and a placebo was administered to two subjects. The purpose of the study was to test the safety of single-dose intravenous drip administration of XYZ, estimate the range of safe dosage, and examine the movement of the test substance.

Safety:
A total of 40 instances of side effects were observed in 10 subjects (23 instances in 2 subjects [1.0 mg/kg group], 5 instances in 2 subjects [2.0 mg/kg group], and 12 instances in 6 subjects [3.0 mg/kg group]). A total of 20 instances of clinical symptoms were observed in 3 subjects (14 instances in 1 subject [1.0 mg/kg group] and 6 instances in 2 subjects [3.0 mg/kg group]). These symptoms were symptoms that accompany the inflammation of the salivary glands and the common cold. It was assumed that the former type of symptoms appeared after the administration of XYZ and were possibly due to latent infections. A total of 20 abnormal fluctuations of clinical examination data were observed in 10 subjects (8 instances in 2 subjects [1.0 mg/kg group], 5 instances in 3 subjects [2.0 mg/kg group], and 7 instances in 5 subjects [3.0 mg/kg group]). In addition to the abnormal fluctuations of clinical examination data caused by the inflammation of the salivary glands and the common cold, the following were observed:

1) An increase of white blood cells in urine in the 1.0 mg/kg group
2) A temporary decrease of white blood cells and neutrophilic leukocytes and a temporary increase of lymphocytes (limphocyte ratio) in the 2.0 mg/kg and 3.0 mg/kg groups

Movement of the test substance:
The movement of XYZ was observed to be nonlinear. Excretion of XYZ in urine could not be observed.

Conclusion:
The side effects observed in this study indicated that administration of XYZ possibly lowers resistance to infection. However, no serious symptoms were observed. The clinical examination data partially showed dose-dependent fluctuations that indicated pharmacological action of XYZ, but no clinically problematic symptoms dependent on the fluctuations were found.