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论文

遗传偏差在新药临床试验中勿容忽视

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摘要：

目的：研究临床药理实验室数据库中的受试者是否有遗传偏差。方法：对数据库中的受试者和随机组织的受试者进行了CYP2D6基因分型对照研究。结果：CYP2D6慢代谢者在136位随机受试者中有9人（6.6%），而在138位临床药理实验室数据库的受试者中只有1人（0.7%），两组经统计有显著性差异。推测慢代谢者因易于体会到药物毒副作用，而易于从数据库中退出，造成数据库中受试者的遗传偏差。结论：新药试验时的受试者应随机组织或对其进行基因分型分析，以确保无遗传偏差。

关键词： 细胞色素P450 2D6 新药临床试验 遗传偏差

GENETIC BIAS COULD NOT BE IGNORED IN CLINICAL TRIALS

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Abstract:

AIM: To evaluate if there is a genetic bias in clinical trials. METHODS: Genotyping of the CYP2D6A, CYP2D6B, CYP2D6D, CYP2D6E and CYP2D6T alleles were subjected to a group of randomly selected volunteers and a group of volunteers from established database of clinical contract laboratories. RESULTS: Nine CYP2D6 enzyme deficient subjects (9/136=6.6%) were found from the 136 randomly selected volunteers and only one (1/138=0.7%) was found in 138 volunteers from established database. There was an extremely significant statistic difference (X^2=6.76, P<0.01) between the two groups. One possible explanation for such an observation is that volunteers deficient in CYP2D6 enzyme activity are more prone to experience adverse effects when participating in clinical trials and are more prone to leave the database, then a genetic bias is made. CONCLUSION: It is strongly suggested that in clinical trials randomly selected volunteers should be used or genetic testing should be subjected to guarantee the genetic make-up of the volunteers.

Keywords: clinical trial genetic bias cytochrome P450 2D6

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