Introduction

Finafloxacin (FIN), a fluorinated quinolone (FQ) with activity both in vitro and in vivo against a wide range of pathogens, is a novel investigational drug for the treatment of bacterial infections. The study was designed to evaluate the safety, tolerability and pharmacokinetic profiles of single and multiple doses of FIN administered intravenously to healthy male and female subjects aged between 18 and 55 years. Subjects received single doses of 200, 400, 600, 800 or 1000 mg intravenously and multiple doses on day 7 of FIN.

Methods

The study was an inpatient, randomized, double-blind, placebo-controlled, dose-escalating study to evaluate the safety, tolerability and pharmacokinetic profiles of single and multiple doses of FIN administered intravenously to healthy male and female subjects aged between 18 and 55 years. Subjects received single doses of 200, 400, 600, 800 or 1000 mg intravenously and multiple doses on day 7 of FIN.

Results

The PK values for subjects receiving single doses are tabulated in Table 2. Plasma concentrations vs. time profiles of escalating single doses are shown in Figures 1 and 3. The PK values for subjects receiving multiple doses are tabulated in Table 3. Plasma concentrations vs. time profiles of escalating multiple doses are shown in Figures 4 and 5.

Conclusions

This FIN Phase I study in healthy subjects revealed a favorable pharmacokinetic profile with high values for C_{max} and AUC_{0-24h} for FIN. No serious adverse events were recorded in the study.

Literature