A Phase 2 Study of the Safety and Efficacy of Oral Delafloxacin (DLX) in Community Acquired Pneumonia (CAP)

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Abstract

Presented with recent respiratory illness consistent with diagnosis of CAP Subjects requiring immediate therapy prior to cu

DLX was an investigational fluoroquinolone active against both positive and negative bacteria, including methicillin- and quinolone-resistant strains of Pseudomonas aeruginosa (PA). The objective of the study was to determine the safety and efficacy of DLX for the treatment of 300 subjects diagnosed with CAP. 300 subjects were enrolled and randomized in a 3:1 DLX treatment group (n: 106) to the control group (n: 34). In addition, DLX has good activity against gram-negative organisms that are usually resistant to fluoroquinolone. Antimicrob Agents Chemother 2003; 47:3260-3269. Epub 2003 Aug 21.

Methods

Introduction

Clinical efficacy rates at visit 4 (test of cure) by dose

Clinical response definitions

The objective was to determine the safety and efficacy of DLX for the treatment of 300 subjects diagnosed with CAP. 300 subjects were enrolled and randomized in a 3:1 DLX treatment group to the control group. The inclusion criteria included all patients aged 50 years or older, with acute respiratory illness consistent with pneumonia on chest radiograph and at least one of the following: tachypnea, cough, and/or dyspnea. The exclusion criteria included all patients aged 50 years or older, with acute respiratory illness consistent with pneumonia on chest radiograph and at least one of the following: tachypnea, cough, and/or dyspnea. The objective was to determine the safety and efficacy of DLX for the treatment of 300 subjects diagnosed with CAP. 300 subjects were enrolled and randomized in a 3:1 DLX treatment group to the control group. The inclusion criteria included all patients aged 50 years or older, with acute respiratory illness consistent with pneumonia on chest radiograph and at least one of the following: tachypnea, cough, and/or dyspnea. The exclusion criteria included all patients aged 50 years or older, with acute respiratory illness consistent with pneumonia on chest radiograph and at least one of the following: tachypnea, cough, and/or dyspnea.

Clinical efficacy rates at visit 4 (test of cure) by dose

Table 3. Microbiological Efficacy Rates at Visit 4 (Test of Cure) by Dose

The objective was to determine the safety and efficacy of DLX for the treatment of 300 subjects diagnosed with CAP. 300 subjects were enrolled and randomized in a 3:1 DLX treatment group to the control group. The inclusion criteria included all patients aged 50 years or older, with acute respiratory illness consistent with pneumonia on chest radiograph and at least one of the following: tachypnea, cough, and/or dyspnea. The exclusion criteria included all patients aged 50 years or older, with acute respiratory illness consistent with pneumonia on chest radiograph and at least one of the following: tachypnea, cough, and/or dyspnea.

Clinical efficacy rates at visit 4 (test of cure) by dose

Table 4. Patient Demographics for Phase 2 CAP Study

Conclusions

No statistically significant dose-response trends and no statistically significant pair-wise differences were observed across the three dose levels of DLX.

All three doses of DLX eradicated established CAP pathogens at a high rate of 85 – 100%. The incidence of all treatment-emergent adverse events was 43% in the 100 mg group, 40% in the 200 mg group, and 43% in the 400 mg group. In all treatment groups, no patients were prematurely discontinued due to adverse events.

There were no patient deaths and no clinically meaningful patterns of laboratory values and vital sign changes during the study.

All three doses of DLX were safe and well tolerated in enhancing or improving clinical signs and symptoms of CAP, eradicating the target pathogens, and enhancing or improving radiographic evidence of pneumonia.

References


