ABSTRACT

Background: Delafloxacin (DLX) is a broad-spectrum, nonsusceptible fluoroquinolone with a novel mechanism of action that has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of complicated skin and skin structure infections (cSSSI) and complicated urinary tract infections (cUTI). The efficacy and safety of IV DLX monotherapy have been studied in the treatment of ABSSSI, but the results of phase 3 clinical studies are not consistent.

Purpose: To compare the efficacy and safety of IV DLX monotherapy to that of IV VAN/AZ in a randomized, double-blind, double-dummy, non-inferiority Phase 3 study.

Methods: A multicenter, double-blind trial of adults with ABSSSI was conducted in 16 countries in Europe and the United States. Baseline bacterial isolates were collected from 820 patients at 113 centers and susceptibility testing of bacterial isolates was performed. Efficacy was assessed using the investigator-assessed criteria of clinical and bacteriological response. Symptoms at EOT, FU and LFU visits were assessed.

RESULTS: Results showed that DLX was non-inferior to VAN/AZ in both objective and clinical response. Areas of erythema and induration were measured with digital planimetry.

CONCLUSION: This study suggested that DLX is non-inferior in efficacy and safety to VAN/AZ in the treatment of ABSSSI.

INTRODUCTION

Infections of the skin and skin structures are common and a significant cause of medical burden. Treatment options are limited, and ear and wound infections have become a major health concern due to the rise of antibiotic resistance. Delafloxacin (DLX) is a non-zwitterionic fluoroquinolone that has been shown to have a broad spectrum of activity against Gram-negative and Gram-positive bacteria.

MATERIALS AND METHODS

STUDY DESIGN

A multicenter, double-blind trial of adults with ABSSSI. Baseline bacterial isolates were collected from 820 patients at 113 centers and susceptibility testing of bacterial isolates was performed. Infections were caused by both Gram-positive and -negative bacteria. The clinical response was assessed using the investigator-assessed criteria of clinical and bacteriological response. Symptoms at EOT, FU and LFU visits were assessed.

RESULTS

Results showed that DLX was non-inferior to VAN/AZ in both objective and clinical response. Areas of erythema and induration were measured with digital planimetry.

CONCLUSION

This study suggested that DLX is non-inferior in efficacy and safety to VAN/AZ in the treatment of ABSSSI.

REFERENCES

