EVALUATION OF DIGITAL VERSUS MANUAL MEASURES OF LESION SIZE IN A PHASE 3 TRIAL OF DELAFLOXACIN (DLX) IN PATIENTS WITH ACUTE BACTERIAL SKIN AND SOFT TISSUE INFECTIONS (ABSSSI)

M. Jafarri1, D. Patel1, L. Lawrence1, M. Quintas1, C. Tseng2, S. Cammarata1
1Molina Therapeutics, Inc., New Haven, CT, 2H2O Clinical LLC, Hunt Valley, MD

ABSTRACT

Background: The primary endpoint in the FDA Guidance on evaluation of endpoints for acute bacterial skin and skin structure infections (ABSSSI) is lesion size or lesion index. Clinical endpoints of lesion size have been an integral part of lesion size or lesion index. Data points were evaluated and compared to assess the digital versus manual lesion size measures. Methods: ACC clinical trial (ADEFIC-001) compared the digital and manual lesion size measures. Lesion size measures were performed at baseline, 24 hours after the start of treatment, and at other defined time points during treatment of ABSSSI. Lesion size estimates were made by digital photography using the standardized protocol. Lesion size was defined as the area of the least squares circle that passed through the lesion. Lesion size was then calculated for all lesions using the equation of the circle. RESULTS: ADEFIc001 was designed to determine the efficacy and safety of the drug Delafloxacin for the treatment of ABSSSI. The primary endpoint was the change in lesion size from baseline to 48 hours. The secondary endpoints included the safety profile and the clinical outcomes. The study was conducted at 20 clinical sites in the United States. The data was analyzed using the paired t-test and the results were compared with the baseline values. The digital lesion size measurements were significantly lower than the manual measurements. The mean difference in lesion size between digital and manual measurements was 1.2 square centimeters. The correlation coefficient between digital and manual measurements was 0.85, which indicates a strong correlation between the two methods. The results showed that digital lesion size measurements are more accurate and reproducible than manual measurements. CONCLUSION: Digital lesion size measurements are more accurate and reproducible than manual measurements. The digital measurements can be used for clinical trials to evaluate the efficacy and safety of new drugs for the treatment of ABSSSI. The results can be used to design future studies and to improve the accuracy of lesion size measurements.