

Title: A Prospective, Randomized, Double-Blind, Multicenter Study to Establish the Safety and Tolerability of Doripenem Compared with Cefepime in Hospitalized Children with Complicated Urinary Tract Infections

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Synopsis:

Doripenem for injection (JNJ-38174942, S-4661) is a sterile, synthetic, parenteral antibiotic of the carbapenem class of β -lactam antibiotics with broad-spectrum, potent antibacterial activity against aerobic and anaerobic gram-positive and gram-negative bacteria. Doripenem exerts its activity by targeting penicillin-binding proteins to inhibit the biosynthesis of the bacterial cell wall.

Doripenem is approved for use in patients 18 years of age or older in the United States for the treatment of complicated intra-abdominal infection (cIAI) and complicated urinary tract infection (cUTI), including pyelonephritis, and in the European Union, Canada, Australia, and in several countries in South America and the Asia-Pacific region for the treatment of cIAI, cUTI, and nosocomial pneumonia (NP), including ventilator-associated pneumonia (VAP). Doripenem is marketed under the trade names DORIBAX® and DORIPREX®.

This study is 1 of 3 separate clinical studies that will be conducted concurrently to establish the safety and tolerability of doripenem when administered as a 60-minute infusion in hospitalized children 3 months to <18 years of age who require intravenous (IV) antibiotic therapy for cIAI, cUTI, or pneumonia.

Primary Objective

The primary objective of this study is to establish the safety and tolerability profile of doripenem compared with that of cefepime in hospitalized children 3 months to <18 years of age with cUTI.

Secondary Objectives

The secondary objectives are:

- To determine the clinical cure rate of doripenem compared with that of cefepime at the test-of-cure (TOC) visit
- To determine the favorable microbiological response rate of doripenem compared with that of cefepime at the TOC visit
- To determine the clinical improvement rate of doripenem compared with that of cefepime at the end of treatment with IV study drug therapy (EIV) visit
- To determine the favorable microbiological response rate of doripenem compared with that of cefepime at the EIV visit
- To determine the sustained clinical cure rate of doripenem compared with that of cefepime at the late follow-up (LFU) visit
- To determine the favorable microbiological response rate of doripenem compared with that of cefepime at the LFU visit
- To characterize the pharmacokinetics of doripenem in hospitalized children with cUTI based on a sparse pharmacokinetic sampling scheme