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CC-CHOC Pediatric Point Person Project (P4)

Protocol Information Form

Follow this link to indicate your interest in Protocol **#13.14 ABSSSI** https://redcap.ctsacentral.org/surveys/?s=7Gifps

Submitted 2012-06-01

Participant ID #13.14 ABSSSI

Sponsor CRO

Study Title A Multicenter, Randomized, Observer-Blinded, Active-Controlled Study to Evaluate the Safety, Tolerability, Efficacy, and Pharmacokinetics of Study Drug Versus Comparator in Pediatric Subjects With Acute Bacterial Skin and Skin Structure Infections

Target Population Pediatric subjects ages 2 months to < 18 years with acute bacterial skin and skin structure infections (ABSSSI)

Study Objectives **Primary:**
Evaluate the safety and tolerability of study drug versus comparator in pediatric subjects
Secondary:
• Evaluate the efficacy of study drug versus comparator in pediatric subjects
• Evaluate the pharmacokinetics of study drug in pediatric subjects with ABSSSI

Key Inclusion/Exclusion Criteria **Inclusion:**
•Presence of ABSSSI warranting 3 days of initial hospitalization and a minimum of 3 days of IV antibacterial therapy, but no more than 14 days of total therapy (IV and PO combined)
•Presence of ABSSSI with measurable margins of erythema (cellulitis)
•Presence of at least 1 of the following local signs and symptoms of acute infection (present for < 10 days):
• Purulent or seropurulent drainage or discharge
• Induration/edema
• Fluctuance
• Heat or localized warmth
AND the presence of at least 1 of the following systemic signs:
• Fever
• WBC count > 12,000/mm3
• > 10% immature neutrophils (bands) regardless of total peripheral WBC
Exclusion:
•Documented history of any hypersensitivity or allergic reaction to vancomycin, aztreonam, or any β-lactam antimicrobial
•Uncomplicated skin and soft tissue infections
•Skin and skin structure infections with a high cure rate
•Skin and soft tissue infections with any of the following characteristics:

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• Known or suspected anaerobic pathogens, Pseudomonas, Proteus, or extended-spectrum β-lactamase-producing organisms
• Known or suspected fungal, parasitic, or viral pathogens as the cause for the ABSSSI
• Decubitus ulcer or diabetic foot infection
• Complicated by osteomyelitis, septic arthritis, or endocarditis
• Burn wound
• Underlying inflammatory skin disease
• Human or animal bite
• Rapidly necrotizing process
• Gangrene
• Presence of prosthetic materials
• Need for amputation
•More than 24 hours of any systemic antibacterial therapy within 96 hours before randomization-NOTE: There are exceptions
•Requirement for any potentially effective concomitant systemic antibacterial therapy
•History of seizures
•Creatinine clearance < 50 mL/min/1.73 m2 as calculated using the updated Schwartz "bedside" formula
•Clinical signs or suspicion of meningitis
•Current septic shock or acute hemodynamic
•Evidence of significant hepatic, hematologic, or immunocompromising condition
•Evidence of immediately life-threatening disease, progressively fatal disease, or life expectancy of ≤ 3 months

Short Study Synopsis Phase 4 multicenter, randomized, observer-blinded, active control study of intravenous (IV) study drug versus vancomycin (or cefazolin) plus optional aztreonam in pediatric subjects from ages 2 months to < 18 years with ABSSSI. A switch to cephalexin (or clindamycin or linezolid) administered by mouth (PO) may be allowed. Total duration of IV plus PO therapy is 5 to 14 days; a minimum of 3 days of IV therapy is required.

Total Number of Patients to be Enrolled 270

Enrollment Period Through March 2014

Miscellaneous Details/Requirements Blinded Observer

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Any question? Email ctsa_childhealth@ctsaC4.org