Article details

Title of article

Ceftobiprole versus daptomycin in *Staphylococcus aureus* bacteremia: a novel protocol for a double-blind, Phase III trial

Authors

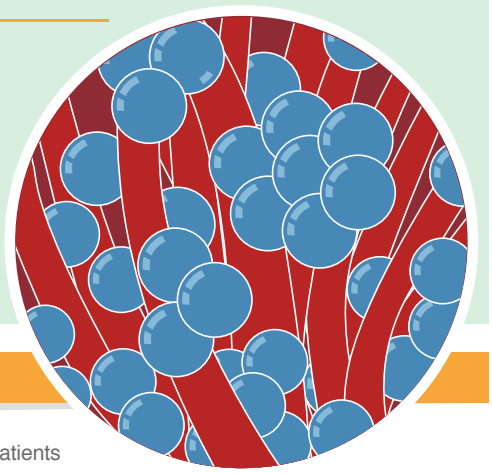
Kamal Hamed, Marc Engelhardt, Mark E Jones, Mikael Saulay, Thomas L Holland, Harald Seifert & Vance G Fowler Jr

Article URL

www.futuremedicine.com/doi/10.2217/fmb-2019-0332

Trial registration number

NCT03138733



Study objectives

Primary objective

Demonstrate non-inferiority of ceftobiprole to daptomycin in the treatment of *S. aureus* bacteremia, including infective endocarditis

Secondary key objectives

Compare ceftobiprole with daptomcyin in relation to all-cause mortality, microbiological eradication rates, time to bacteremia clearance, development of new metastatic foci or complications, and safety and tolerability; assess the pharmacokinetics of ceftobiprole

Key inclusion criteria

- Hospitalized male or female patients ≥18 years
- *S. aureus* bacteremia based on ≥1 positive blood culture obtained within 72 h prior to randomization
- Signs or symptoms of bloodstream infection
- Confirmed or suspected complicated *S. aureus* bacteremia, or definite native-valve right-sided infective endocarditis according to Modified Duke Criteria

Study design

Randomized 1:1

Double-blind Double-dummy

Phase III

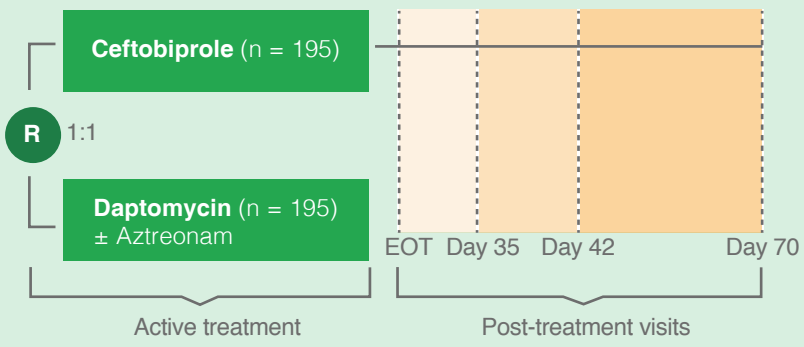
>80 global sites

13 countries

~390 patients

Eligible patients are randomized 1:1 to ceftobiprole or daptomycin

Concomitant use of non-study systemic antibacterials with activity against *S. aureus* is prohibited from randomization up to the Day 70 (±5 days) visit



Primary end point

Overall success, defined by the following criteria being met:

- Patient alive at Day 70 (±5 days) post-randomization
- No new metastatic foci or complications of the *S. aureus* bloodstream infection
- Resolution or improvement of *S. aureus* bacteremia clinical signs and symptoms
- Two negative blood cultures for *S. aureus*, without any subsequent positive blood culture for *S. aureus*:
  - ≥1 negative blood culture must be recorded while the patient is on active study treatment
  - Cultures must be confirmed by ≥1 subsequent negative blood culture for *S. aureus* at Day 70 (±5 days) or between 7 days after the end-of-treatment visit and Day 70 (±5 days)

Study period

August 2018 to second half of 2021