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Treatment outcomes in candidaemia and/or invasive candidiasis among patients receiving rezafungin or caspofungin while the fungal culture was still positive

06. Fungal infection & disease

6d. Antifungal drugs & treatment (incl. clinical trials)

Likely attendance

Onsite

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Background

The Phase 3 ReSTORE trial (NCT03667690) demonstrated non-inferiority of rezafungin against caspofungin for Day 30 all-cause mortality (ACM) and Day 14 global cure in subjects with candidaemia/invasive candidiasis (C/IC) (1). The current analysis examined ReSTORE data for those subjects with a positive culture proximal to randomisation to understand the potential impact on efficacy outcomes.

Methods

ReSTORE comprised a global, randomised, double-blind, double-dummy, Phase 3 non-inferiority trial. Adults (aged ≥18 years) with C/IC received rezafungin once-weekly intravenous infusion (Week 1: 400 mg; Weeks 2–4: 200 mg) or once daily caspofungin (Day 1: 70 mg; Days 2–28: 50 mg) for ≥14 days and ≤4 weeks. The current post hoc analysis examined data for a subgroup of patients that had positive blood culture ≤12 hours prior to or ≤72 hours following randomisation, or positive culture from another normally sterile site ≤48

hours prior to or ≤72 hours after randomisation. Efficacy endpoints included Day 30 ACM as well as global cure (assessed by an independent data review committee [DRC]) and mycological response on Days 5 and 14.

Results

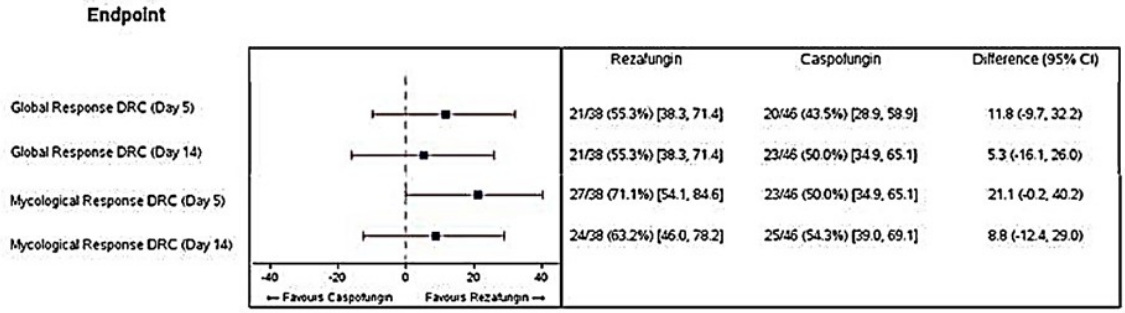
The analysis included 38 participants treated with rezafungin and 46 subjects receiving caspofungin. Day 30 ACM rate was 26.3% (rezafungin arm) and 21.7% (caspofungin arm), with a difference in outcome (95% confidence interval [CI]) of 4.6 (-13.7, 23.5). DRC-evaluated Day 14 global response was 55.3% with rezafungin and 50.0% with caspofungin (difference [95% CI]: 5.3 [-16.1, 26.0]). DRC-assessed Day 5 mycological response was 71.1% (rezafungin arm) and 50.0% (caspofungin arm). The between-group difference (95% CI) was 21.1 (-0.2, 40.2; Figure 1).

Conclusions

Assessment of clinical outcomes from ReSTORE trial subjects with a positive culture proximal to randomisation showed that Day 30 ACM and Day 14 global response remained comparable between rezafungin and caspofungin treatment groups. Day 5 mycological response was 71.1% and 50.0% with rezafungin and caspofungin, respectively.

Figure 1

Figure 1. Treatment outcomes following administration of rezafungin (400 mg/200 mg) or caspofungin (70 mg/50 mg) for those subjects with a positive culture closer to randomisation



Analysis based on a subgroup of subjects diagnosed with candidaemia and/or invasive candidiasis by blood culture ≤12 hours prior to or ≤72 hours following randomisation, or via culture from another normally sterile site ≤48 hours prior to or ≤72 hours after randomisation. Subjects received either rezafungin once-weekly (QWk) intravenous injection (Week 1: 400 mg; Weeks 2–4: 200 mg) or once daily (QD) caspofungin (Day 1: 70 mg; Days 2–28: 50 mg) for ≥14 days (≤4 weeks).
Abbreviations: CI, confidence interval; DRC, independent data review committee.

Keyword 1
Clinical trials
Keyword 2
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1. Thompson GR et al. Rezafungin versus caspofungin for treatment of candidaemia and invasive candidiasis (ReSTORE): a multicentre, double-blind, double-dummy, randomised phase 3 trial. Lancet. 2022 Nov 25:S0140-6736(22)02324-8.
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Conflicts of interest

Do you have any conflicts of interest to declare?
Yes
Honoraria or consultation fees
Personal grants/research supports
Institutional grants/research supports
I hold stock or stock options in companies in the medical field