

## Prematurely ended study

**EudraCT number:** 2013-005583-25

**Sponsor code:** COLIMERO

### **Title:**

Multicenter, randomized, open label, controlled clinical trial that compares the efficacy of the combination of colistin and meropenem versus monotherapy for the treatment of bacteremia and pneumonia due to *Pseudomonas aeruginosa* extremely resistant with reduced sensitivity to meropenem

This study was prematurely ended for the following reasons:

- Very low recruitment rate due to a lower number of evaluable cases than expected in many centers, and due to the high complexity of the cases which have been evaluated. Only 9 cases were recruited out of the 150 expected in 9 months. This study was requested in a 2013 Spanish grants call. The caseload forecasts to reach the calculated sample size were made with data from 2012 and previous years. The study, after the selection process and paperwork with the 14 centers, CEICs and Spanish medicines agency began recruitment in January 2015. It is several years after the forecasts were made, and in this time the epidemiology and casuistry of this infection had changed. Moreover, there were fewer cases of invasive infection, and cases with colonization and other exclusion criteria maintained or increased.
- This rate of recruitment prevented the study from being completed in the time initially planned and even if an extension of one and a half years were requested (total of 3 and a half years of recruitment) it would not be possible to complete the study. Therefore, it was prematurely ended in 2015.

However, although patients could not be recruited for the clinical trial, some microbiological results could be analysed and published:

Del Barrio-Tofiño E, López-Causapé C, Cabot G, Rivera A, Benito N, Segura C, Montero MM, Sorlí L, Tubau F, Gómez-Zorrilla S, Tormo N, Durá-Navarro R, Viedma E, Resino-Foz E, Fernández-Martínez M, González-Rico C, Alejo-Cancho I, Martínez JA, Labayru-Echverría C, Dueñas C, Ayestarán I, Zamorano L, Martínez-Martínez L, Horcajada JP, Oliver A. Genomics and Susceptibility Profiles of Extensively Drug-Resistant *Pseudomonas aeruginosa* Isolates from Spain. *Antimicrob Agents Chemother*. 2017 Oct 24;61(11):e01589-17. doi: 10.1128/AAC.01589-17. Erratum in: *Antimicrob Agents Chemother*. 2017 Dec 21;62(1): PMID: 28874376; PMCID: PMC5655108.

Signed

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