Trials 2019, **20**(Suppl 1):579
https://doi.org/10.1186/s13063-019-3688-6

Trials

MEETING ABSTRACTS Open Access

Meeting abstracts from the 5th International Clinical Trials Methodology Conference (ICTMC 2019)

Brighton, UK. 06-09 October 2019

Published: 22 October 2019

P-261

The importance of continued follow-up in cancer trials: results from the TEAMM myeloma trial assessing the benefit of 12 weeks levofloxacin prophylaxis on febrile episodes or deaths

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Trials 2019, **20(Suppl 1):**P-261

Introduction: Myeloma causes profound immunodeficiency and recurrent, serious infections. There are approximately 5,500 new UK cases of myeloma per annum; a quarter will have a serious infection within 3 months of diagnosis. Newly diagnosed patients may benefit from antibiotic prophylaxis to prevent infection and early death but this may be associated with healthcare-associated infections

Methods: The Tackling Early Morbidity and Mortality in Myeloma trial (TEAMM) trial was a multicentre randomised, double-blind, placebo-controlled trial in newly-diagnosed myeloma patients randomised to receive Levofloxacin or placebo for 12 weeks at the start of anti-myeloma treatment. Follow-up was 4-weekly to 16 weeks and again at 1 year. The composite primary outcome was defined as time to first febrile episode or death in the first 12 weeks from start of trial treatment. Secondary outcomes included overall survival at 16 weeks up to 12 months.

Results: 977 patients were randomised (489 levofloxacin, 488 placebo). Primary events (febrile episodes, deaths, febrile episodes with death) in levofloxacin versus placebo arms were 19% vs 27% (87, 4, 4 vs 112, 15, 7), respectively; HR=0.66 (95% CI 0.51-0.86) p=0.002. There was a benefit in overall survival at 12 weeks (p=0.008) but not at 12 months (p=0.94).

Conclusions: The use of 12 weeks prophylactic antibiotics significantly reduced the number of febrile episodes or deaths within the first 16 weeks. However, this did not predict longer-term survival. Models to adjust for additional treatments indicated that the use of co-trimoxazole was independently associated with improved survival. TEAMM demonstrates the need for longer-term follow-up in cancer trials. This has influenced the design of TEAMM2 trial.