

4th World Congress on

Rare Diseases and Orphan Drugs

June 11-12, 2018 | Dublin, Ireland

The safety and efficacy of prednisolone in preventing re-accumulation of ascites among endomyocardial fibrosis patients in Uganda: A randomised clinical trial

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Background: Endomyocardial fibrosis (EMF), the commonest restrictive cardiomyopathy worldwide, is characterized by obliterative inflammation and fibrosis of the endocardium. Inflammation in other parts of the body such as the peritoneum may explain the accumulation of ascites, a painful and disabling feature of this disease. Therefore, we aimed to determine the efficacy and safety of prednisolone to prevent re-accumulation of ascites from International Ascites Club grade 2 to grade 3 among EMF patients attending Mulago Hospital's cardiology service.

Methods: This was a randomised placebo controlled trial with a 1:1 parallel design. Over a period of ten months, participants were recruited and randomized to receive 1 mg/kg per day of prednisolone or placebo and were followed for a maximum of 8 weeks. The primary outcome was re-accumulation of grade 3 ascites. Safety was assessed by self-reported side effects, physical exam and laboratory assessment.

Results: Sixteen patients were randomised to prednisolone, while 19 were randomised to placebo. Six patients were lost to follow up (1-prednisolone arm, 5-placebo). Baseline characteristics were balanced between groups, although only 4% had exudative ascites and only 10% had eosinophilia overall. Prednisolone was safely administered in this setting; however, there was no statistically significant difference in the overall risk of developing grade 3 ascites over 8 weeks (RR (95% confidence interval) 0.70 (0.439-1.114), p=0.12). The rate of the primary outcome per 1000 persons, after days of follow-up was also similar in both groups (p=0.63).

Conclusion: Short term prednisolone use was generally safe in this patient population; but there was no statistically significant evidence of efficacy. Additional studies are needed to assess the efficacy of anti-inflammatory treatments to slow progression of this disease.

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