ERTAPENEM ADMINISTERED SUBCUTANEOUSLY VERSUS INTRAVENOUSLY FOR URINARY TRACT INFECTIONS IN ONCOLOGY PALLIATIVE CARE PATIENTS: PRELIMINARY DATA OF A RANDOMIZED, OPEN, NON-INFERIORITY CLINICAL TRIAL

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INTRODUCTION

Infections requiring intravenous antimicrobial therapy are very common in patients with advanced cancer. Nevertheless, these patients frequently present vascular damages becoming extremely difficult to access and maintain the intravenous route. The subcutaneous route could be implemented for replacement of fluids, electrolytes and drugs. Few studies have evaluated subcutaneous route for treatment of infections though. Thus, we hypothesize Ertapenem subcutaneously is not inferior to the same drug intravenously for the treatment of urinary tract infections (UTI) in patients on oncologic palliative care, with important advantages such as greater convenience of use. Our objectives are to describe the characteristics of the first year patients recruited.

METHODS

This is a phase 3, randomized open-label clinical trial to evaluate if Ertapenem administered subcutaneously is non-inferior to the same antibiotic intravenously to treat UTI in oncological palliative care patients. The study has been performed since April 2017 and is still recruiting. The primary outcome is the microbiological cure at the end of treatment. The secondary outcomes are infusion related adverse events and clinical response.

RESULTS

The study enrolled in one year 19 patients, 68% with lower UTI, 47% had at least one urinary infection in the previous three months. The median age was 54 years and 74% were women; 53% of them were the Palliative Prognostic Score B. Thirty percent (63%) was the most common Karnofsky Performance Status. The median leukocyte count was 11,200/µl and the median C - reactive protein was 11,2mg/dl. Half of them were randomized to receive Ertapenem subcutaneously, seven days was the median time of use. None side effect was observed. Escherichia coli (53%) was the most common pathogen isolated in the urine culture. At the end of the treatment, 89% had the microbiological cure and all patients that informed theirs symptoms referred improvements, including dysuria and suprapubic pain.

Demographic and clinical baseline characteristics in the intention-to-treat population

Characteristic, n (%)	Intravenous (%) N = 10	Subcutaneous (%) N = 9	*P*-value*
Gender			
Female	8 (80)	6 (66)	0.63
Male	2 (20)	3 (33)	
Age in years, median (range)	50 (35 -84)	56 (31 – 74)	0.22
Device (urinary catheter or percutaneous nephrostomy)	8 (80)	4 (44)	0.17
Corticosteroid use	6 (60)	6 (66)	0.99
Diabetes Mellitus	0 (0)	3 (33)	0.09
UTI within the last 3 months	5 (55)	4 (44)	0.99
UTI classification			
-High	6 (60)	0 (0)	0.01
-Low	4 (40)	9 (100)	
White cell count 10^3/µl, median, (range)	12,3 (6,1 – 22,4)	8,7 (4,0 – 16,5)	0.05
Creatinine clearance, mL/min, median, (range)	49.3 (16.3 -328.6)	102.8 (30.2 -254.5)	0.99
C-reactive protein, median, (range)	13.9 (4.84 – 31.4)	5.8 (0.4 – 32.5)	0.21

*Fisher-Exact 2-tailed test for crosstabulation, Mann-Whitney/Wilcoxon test for medians.

CONCLUSION

Preliminary data show the use of Ertapenem subcutaneously for UTI can be safe and effective. Clinical Trials Registration: NCT03218800.

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