

## Results

The following section describes the results of the study by calculating means and standard deviations of the drug and placebo groups. These are then compared using the two sided students T test. Further analysis of the primary objective was done using a linear regression model. Aside from the safety data each of the outcomes is discussed.

All analyses are done on an intention to treat basis.

### Number of stools at 48 hours

The difference in the mean number of stools revealed no statistically significant difference between the drug and placebo groups: being  $6.7 \pm 0.7$  stools for the drug and  $6.6 \pm 0.48$  for the placebo (p value = 0.19).

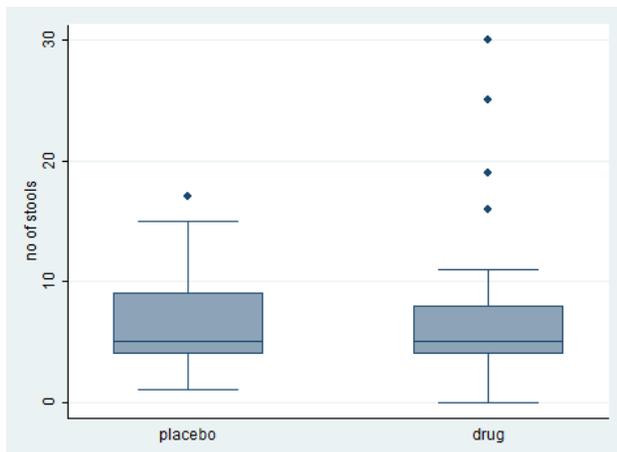


Figure 1. Number of stools in the first 48 hours after introduction of the drug.

### Duration of inpatient stay

This was measured as the number of days from the start of the medication to the day of discharge as determined by the attending physician. The results here on were in favour of the drug (mean of  $5.5 \pm 0.46$

days as compared with  $5.8 \pm 0.62$  days for the placebo). The results were not statistically significant ( $p$  value = 0.48).

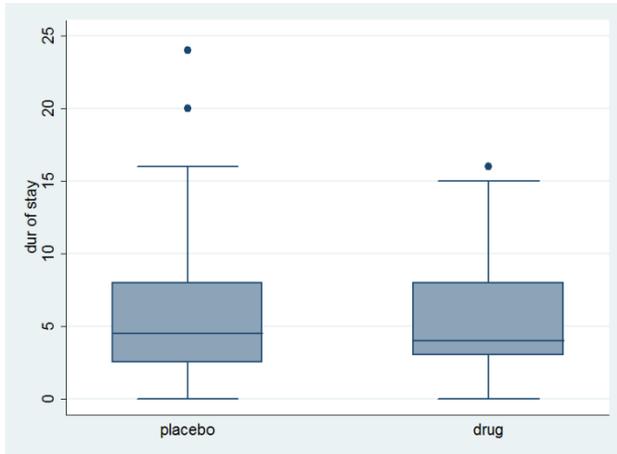


Figure 2. Duration of inpatient stay in days between the drug and placebo groups after introduction of the drug.

#### Duration of illness

The duration of illness, calculated as the duration from the time of introduction of the drug to the appearance of  $\leq 3$  formed stools in 24 hours, was compared across the 2 groups. On analysis the time to heal was similar between the two groups: mean of  $2.7 \pm 0.23$  days for the placebo and  $2.8 \pm 0.25$  days for Racecadotril ( $p$  value of 0.27 on students T test).

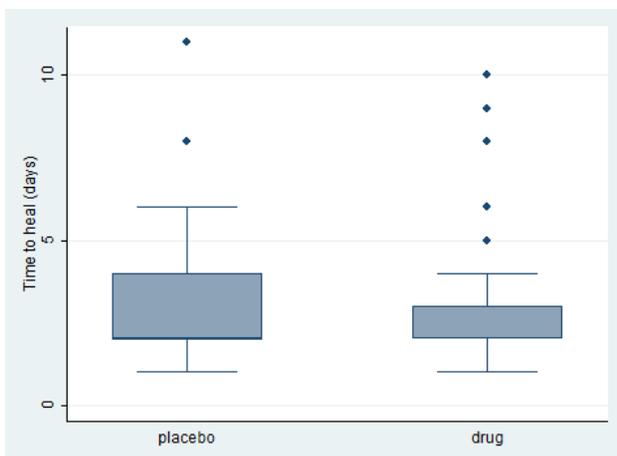


Figure 3. Duration of illness (time to heal) in days between the drug and placebo groups after introduction of the drug.

When linear regression analysis was carried out, the drug did not have a significant effect on any of the outcomes described above even after correction for age, malnutrition, duration of diarrhoea and level of dehydration at admission.

It was noted, however, that malnutrition had a statistically significant effect on duration of inpatient stay in children with severe malnutrition remaining in hospital longer. Children who had a longer duration of diarrhoea before starting the medication also took longer time to heal after introduction of the drug when corrected for other variables.

The graphs below show the survival analysis curves comparing the drug and placebo for the outcomes of duration of inpatient stay and the time to heal. In both graphs the curves intersect confirming no significant advantage of the drug over the placebo.

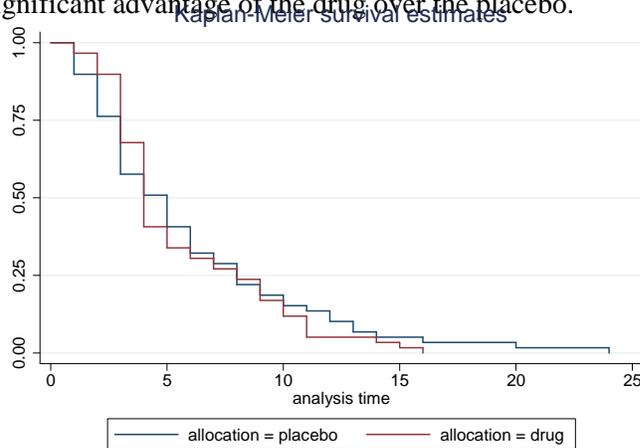


Figure 4: survival analysis curve showing the duration of inpatient stay in both the Racecadotril and placebo groups

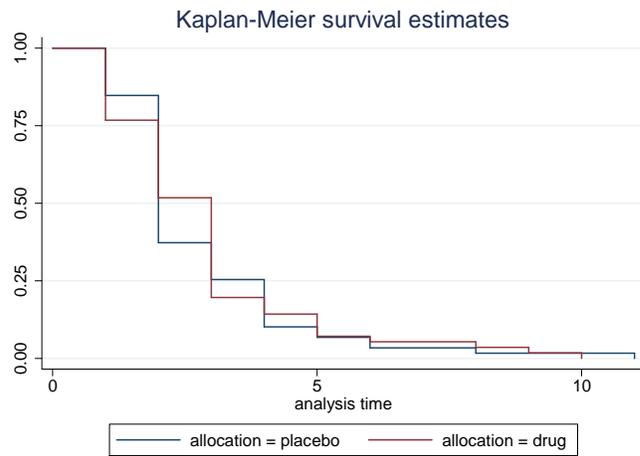


Figure 5: survival analysis curve showing the duration of illness in both the Racecadotril and placebo groups