assessments and regulatory advice and may indicate that current levels of MPB formulations are acceptable for you.

ProSpective Validation Of A MoDEL-based DosIng RegIMEn For aMikacIn In preTerM And Term neonates

Methods Routine amikacin therapeutic drug monitoring (TDM) concentrations were prospectively collected. To test efficacy of the dosing regimen, early observed TDM results (i.e. prior to and 1 h after the second intravenous amikacin dose) reaching target concentrations (t > 3 mg/L, peak > 24 mg/L) were defined. To test stability and accuracy of the model, all observed concentrations were compared with the predicted concentrations and a normalised prediction distribution error (NPDE) was performed. Monte Carlo simulations were used to evaluate amikacin exposure.

Results In total, 1191 TDM results of 579 neonates [median gestational age 34 (range 24–41) weeks, postnatal age 2 (range 1–30) days] were included. Sixty percent of the early trough levels was below 3 mg/L. 90.4% of the peak levels reached 24 mg/L. Compared to the final PK model and the prospective dataset. No trend was seen in the rable parameter estimates were obtained between the final PK model-derived dosing regimen.

Results The median plasma melatonin levels on day 4 was 15.2 pg/ml in the melatonin group and was 0 pg/ml in the saline group. On nonlinear mixed effect modelling, using first order conditional estimation with interaction, the clearance was 0.05 L/hr with a half-life of 15.61 h. Effect of covariates: gender and race were not significant in this study unlike previously reported. Mean melatonin concentrations in donor breast milk were 63 pg/ml higher than that of maternal breast milk even on day 4 (16.6 pg/ml). Conclusions Preterm infants have delayed clearance and prolonged half-life of melatonin. This data can be used for simulation of future dose studies in preterm infants.

Pharmacokinetics Of Melatonin In preTerm infants

Abstract O-109 Table 1

CR(1d) CR(2d) CR(3d) FR(1d) FR(2d) FR(3d)
3%HHS+A 143 143 142 49 49 48 4.13
3%HHS+P 141 142 142 49 47 46 4.17
p 0.76 0.48 0.73 0.88 0.07 0.24 0.89

Conclusions Preterm infants have delayed clearance and prolonged half-life of melatonin. This data can be used for simulation of future dose studies in preterm infants.