Table 2 Parameter estimates and median and 5 - 95 percentile confidence intervals of a bootstrap (n = 1000 simulations) of the final PTTE model predicting the hazard of the restart of an unblinded midazolam infusion due to undersedation in children receiving blinded midazolam or blinded placebo, reported with % relative standard errors (RSE%)

Parameter	Estimate	RSE%	Bootstrap Median	5 - 95 Percentile Confidence Interval
Baseline hazard	0.0373	17%	0.038	0.028 – 0.049
Midazolam	-0.506	22.3%	-0.510	-0.659 – -0.291
PRISM II	-0.0492	31.9%	-0.051	-0.078 – -0.022
Dropout hazard	0.00237	16.9%	0.002	0.002 – 0.003

According to this model, the clinical hazard h for an event (restart of an unblinded midazolam infusion due to undersedation) in children receiving blinded midazolam or blinded placebo is $h(t)=0.037\cdot(1-0.506\cdot Midazolam)\cdot e^{-0.049\cdot(PRISM\ II-16)}$, which is the product of a constant baseline event hazard distribution, and two covariates, i.e. treatment arm ($Midazolam$) and disease severity ($PRISM\ II$¿· $Midazolam=1$ for patients administered blinded midazolam and $Midazolam=0$ for patients administered blinded placebo, and $PRISM\ II$ is a proportional hazard per unit of disease severity (PRISM II score) centered to a median PRISM II score of 16.