

Statistical method:

Analyses will be performed using R.

The primary analysis set is per protocol (PP) as there is an anticipated missingness in timestamped sedation log. Therefore, ITT analyses including all randomized participants with available principal outcome data will be conducted as sensitivity. Continuous variables will be presented as means $\pm$ SD and compared with Student's t test; categorical variables as n (%) with χ^2 tests.

The mean differences between the two groups will be presented with 95% CIs for primary and complete case secondary outcomes. For multiple secondary endpoints, a familywise error using Hochberg's procedure will be conducted. An adjusted analysis (linear model) for the primary endpoint will be performed, including sex, age, and BMI. A twosided $p < 0.05$ will be considered significant.