

22.02.2024

Statistical analysis plan for METACEBO,
NCT04680286

The following plan was decided upon before obtaining A and B list from the Hospital Pharmacy.

Missing data are assumed to be missing at random.

Primary outcomes are opioids (yes/no) within 3 hours following extubation (or until discharge), and highest FLACC-score within 3 hours following extubation (or until discharge).

Primary outcomes will be analyzed paired or unpaired t-test for difference, depending on distribution. For the dichotomous outcome (opioids: yes/no) a χ^2 test will be performed. FLACC scores will be presented visually in a plot with FLACC over time.

Secondary outcomes will be reported with medians (interquartile range) and compared at various time-points between the group using the Mann-Whitney U test.

Outcomes regarding opioid consumption at home and adverse events will be dichotomized and presented with χ^2 test.