

Statistical analysis plan for METAMORF, NCT04475029

Aarhus, September 7th 2023

The following plan for data analysis was decided upon at a meeting with a statistician on September 7th, 2023. The plan was made before A and B lists were obtained from the hospital pharmacy.

This study will be undertaken as an equivalence trial with the application of intention to treat analysis.

Missing data are assumed to be missing at random.

Primary outcome will be analyzed paired or unpaired t-test for difference, depending on distribution.

Analysis of the secondary outcome NRS will be reported as median (interquartile range) and compared between groups at the various times using the Mann–Whitney U test. If normal distributed a multilevel mixed effects linear regression will be carried out.

Analysis of other secondary outcomes will be dichotomized and presented for 3 and 24 hours with χ^2 test.