Optimization of prime fluid strategy to preserve microcirculatory perfusion during cardiac surgery with cardiopulmonary bypass – PRIME study

Record number Clinical Trials.gov	NCT05647200
Date	March 25th, 2025

Explanation of Randomization Process

In the present study, randomization was conducted on the day prior to surgery to ensure sufficient time for the preparation of CPB priming, in line with the logistical requirements of our hospital. While this approach was necessary to meet operational needs, it also introduced several challenges throughout the study.

We encountered frequent changes in surgery dates due to logistical reasons, which led to the use of different types of cardioplegia. As the study was designed as a physiological proof-of-principle study, we aimed to evaluate the effects of CPB prime fluid strategies on microcirculatory perfusion without the potential interference of additional hemodilution associated with crystalloid cardioplegia. Therefore, the study protocol was amended after start of the study to be able to replace already randomized patients if the type of procedure, or surgery date changed, leading to the use of a different cardioplegia and to increase the sample size until all groups had at least 8 patients available for the final analysis. The institutional review board approved this amendment. Due to the replacement of patients and the use of random block sizes of three, six, and nine an uneven distribution of patients across the three study groups occurred. As this was a physiological proof-of-principle study and the replaced and excluded patients were comparable to those included in the final analysis with regard to baseline characteristics we strongly believe that this amendment of the protocol did not influence the findings of this study. (Table 1 and *e*Table1)