

Supplementary notes to the PROVOLON trial statistical analysis plan

Official Title of the trial: Effects of Open Lung Approach on Intraoperative Respiratory Function and Postoperative Recovery of Patients With Laparoscopic Colorectal Resection

Brief Title: The PROtective Ventilation using Open Lung approach Or Not trial
(PROVOLON)

ClinicalTrials.gov ID: NCT03160144

Unique Protocol ID: 2017ZSLYEC-002

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Supplementary notes to the statistical analysis plan

When designing this study, the sample size was calculated manually according to the formula recommended by a statistical experts. We always felt confident with it, so we presented it in the study protocol and trial registration. However, after completion of the study, we found the sample size calculation was wrong. We are deeply sorry and ashamed for this careless mistake.

As there are significant differences between groups in the primary outcome events in this trial, the expansion of sample size may harm the interests of some patients. In addition, we calculated the power of this study based on the effective sample size and the actual incidence of primary outcome at the 0.05 alpha level two-sided and found that it was about 0.8, so the conclusion of this study is still of great significance. After discussion, the research team decided that we would not expand the sample size, and we will publish the results and conclusions of this study with the actual completed sample size of 280 cases.

The cause of the wrong sample size calculation is still unclear after investigation. However, it is certain that the primary outcome incidence in the OLS group should be 10.5% instead of 12.5% (this is very likely to be a writing mistake) as presented in previous registration. Because the design and protocol of the IMPROVE trial¹ was an important reference for this study, and the mechanical ventilation strategy of the OLS group in this study was the same as the "lung-protective ventilation" group in that study¹, the two study populations and primary outcomes are similar. For this reason, we will express the expected incidence of primary outcome in the OLS group as 10.5% in the following publication of the trial.

1. Futier E, Constantin JM, Paugam-Burtz C, Pascal J, Eurin M, Neuschwander A, Marret E, Beaussier M, Gutton C, Lefrant JY, Allaouchiche B, Verzilli D, Leone M, De Jong A, Bazin JE, Pereira B, Jaber S, Group IS: A trial of intraoperative low-tidal-volume ventilation in abdominal surgery. *N Engl J Med* 2013; 369: 428-37