Review of: "Delayed vs Early Umbilical Cord Clamping in 100 Preterm Infants: an RCT from Bhavnagar, Gujarat"

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Potential competing interests: No potential competing interests to declare.

This manuscript compares the umbilical cords of newborns after birth, with randomization for the timing of clamping. Below, I list some points that need to be improved, which I hope you will find helpful. I also refer you to the PRISMA statement (https://www.prisma-statement.org/) and the Cochrane handbook (https://training.cochrane.org/handbook/current/). I am going to point out the quality of your research. Please refer to this as well, if you like.

First, I think it would be a better idea to attach the CONSORT checklist (https://www.consort-statement.org/). In recent literature, most of them ask for the CONSORT checklist to be attached. Since it is effective to construct manuscripts systematically referring to the checklist, I would like to ask you to consider this.

Second, does this RCT have a pre-registration? It should have pre-registered what study design was used for the pre-defined outcomes. If it has not registered, the reason should be stated in the limitation, e.g. ClinicalTrial (https://clinicaltrials.gov/).

[Evaluation of the quality of this study]

Bias arising from the randomization process: The randomization and allocation concealment are properly performed. The baseline between the two counties is also balanced.

Bias due to deviations from intended interventions
Blinding methods are described in detail, and if each staff member adheres to the allocation, there should be no bias problems. However, it should be noted that if there is no study protocol, it is impossible to prove that there is no intentional deviation from the intervention. In addition, as detailed below, it is recommended to add a statement as to whether ITT or PP analysis was conducted.

Bias due to missing outcome data
Since the amount of missing data is not large, the bias is not expected to have a significant impact on the analysis. However, as described below, the reason for the missing data should be stated.

Bias in the measurement of the outcome
I think that the bias in this domain is small because the outcome is objectively measured with little variation.

Bias in selection of the reported result

The intervention of bias cannot be ruled out for this domain. As expected, there is no proof that the outcome was determined in the previous study, which raises the suspicion that the outcome, such as anemia, was reported after the study was terminated. Since this also affects the sample size calculation, the details of what outcome is assumed should be described.

Page 5, Method: How was the sample size calculation performed? In general, it is preferable to determine the primary outcome you wish to obtain in advance, find a clinically meaningful difference, and perform the calculation from there.

Page 8, Result: Are all analyses including dropouts? In other words, do all analyses follow the Intention To Treat principle? Or are Per Protocol analyses performed without including dropouts? Since the number of Lost to Fup is not large, I do not think there is much difference in the final analysis results between ITT and PP, but dropouts are events in which bias is likely to intervene, so caution should be exercised. Therefore, I recommend that you add the following two points: 1) clearly state whether it is ITT or PP and the method of analysis (sorry if I missed it), and 2) provide details on the reason why the dropouts dropped out.