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LETTER TO THE EDITOR

High-dose dexamethasone as the first-line treatment in children with primary immune thrombocytopenia?

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We read the article by Ma and colleagues with great interest and appreciate the authors' efforts [1]. However, we would like to point out several concerns we have regarding this research.

First, they concluded "this study suggested that HDD (high-dose dexamethasone) provides a comparable effective response as a first-line treatment for ITP, with better tolerance than conventional PDN (prednisolone)." This is misleading because the authors indicated in the paper that this study is a non-inferiority trial, but they did not set the inferiority margin and the confidence interval for the difference in means, which is mandatory in examining non-inferiority ahead of analysis. Therefore, this study cannot be defined as a non-inferiority study.

Second, there was a critical discrepancy between study eligibility criteria reported in this paper and those in the trial registration (ChiCTR-INR-16008827), which raised concerns about serious selective reporting biases. On the criteria given in the registry, four intervention groups (HDD, PDN, IVIG [intravenous immunoglobulin] + HDD, IVIG + PDN) were scheduled, but only two groups (HDD and PDN) were described in this paper. Furthermore, there seemed to be two more institutes that participated in this trial, but the authors published it as a single-center trial. If there were any unavoidable reasons to modify the research plan, the authors should mention the details and modified procedure in the paper.

Third, the authors ambiguously pre-specified "effect" and "safety" as their outcomes in the trial registration, which could lead to reporting bias. For example, several adverse events, such as insomnia, mood disorders, or palpitations, were not recorded in this study. These adverse events were reported more frequently in the HDD arm in a previous study [2] and were thought to be easily assessed even in children.

Hence, we are concerned about misinterpretation of the results, selective reporting bias, and a critical discrepancy between the description and the trial registration.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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