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About reporting clinical trials

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major thrombosis and platelet number in this untreated group. Results have shown a hazard ratio (HR) of 0.65 (95% confidence interval [CI] 0.31-1.25; $P = .15$) for patients with a platelet count more than 1000×10^9/L. Thus, a clear, albeit not significant, trend toward "more platelets, less thrombosis" can be observed also in these patients. Overall, we are happy to share with Dr Tefferi the belief that thrombocytosis, per se, should not be taken as a good reason to give cytotoxic chemotherapy to otherwise low-risk ET patients.

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Conflict-of-interest disclosure: The authors declare no competing financial interests.

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To the editor:

About reporting clinical trials

As members of a French research ethics committee, a recent paper on the treatment of multisystem Langerhans cell histiocytosis (MS-LCH) by Gadner et al[1] was brought to our attention. The authors' efforts to conduct an international randomized controlled trial on this orphan disease are worthy but this report leads us to make some comments.

The title and the conclusion of the abstract ("intensified treatment significantly increases rapid response and reduces mortality in risk MS-LCH") do not reflect the main findings of the LCH-II study, albeit adequately presented in the results and discussion sections of the article. This study showed no significant difference for risk patients (ie, with risk organ involvement or age of onset younger than 2 years) between conventional and intensified treatment for the primary (rapid response) and the secondary endpoints (survival probability, disease reactivation frequency, and sequelae). The quality of the trial is not in question; it was adequately designed and conducted to detect a 20% difference in rapid response between the 2 arms, but was underpowered to detect a difference as small as the observed difference (8%).

The abstract's conclusion is based on 2 exploratory analyses. (1) The reduction of mortality in LCH-II arm B versus arm A issued from a subgroup analysis (patients with risk organ involvement) on a secondary end point with an adjustment on the risk organs involved. The justification of this adjustment is not given in the article and the high P value (.049) does not exclude a chance result.[2] (2) The pooled analysis of LCH-I[3] and LCH-II[1] studies is not justified in the article; we do not know whether this pooled analysis was planned a priori or not. Moreover, the tests used in this pooled analysis implicitly assume that there is a continuous intensification of treatment from arm A LCH-I to arm B LCH-II. This assumption is not established: LCH-I compared 2 drugs (vinblastine vs etoposide) without any notion of intensification, and the affirmation that arm A LCH-II was more intensive than arm B LCH-I is debatable, at least in relation with the main criterion (rapid response).

The main message of the LCH-II trial is correctly presented in the discussion: there was no significant effect of treatment intensification for the population included in this study despite encouraging results for patients with risk organ involvement. Despite the low number of controlled studies in this disease, a systematic review[4] of all the available trials could be useful to consolidate the conclusion.[5] We advocate reporting conclusions of clinical trials for themselves with accurate title and abstract in order to prevent any confusion among physicians and offer patients the best return benefits from their contribution.[6]

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