Randomized, placebo-controlled trial

To the Editor: I read with interest the recently published randomized, placebo controlled trial by Kamyabi et al.1 I could not find any statement by the authors confirming that informed consent was obtained from patients subjected to this trial. This is especially important when there is a placebo arm in which patients are not going to receive any pain relief intervention, although pain relief was considered to be “the aim of the obstetrician” as stated by the authors in the introduction of the paper. Thus the placebo-arm patients will be deprived of “the standard of care.” Moreover the authors did not mention if this study was reviewed and approved by any independent institutional review board.

When reviewing some prospective studies on human subjects that were published in the Annals, I was unable to find such statements. The Annals clearly indicates such requirements in its “information for authors” section published regularly with each issue, thus I am confident that the editorial board does not clear any submitted manuscript for publication without having received these important statements from the authors. It may be more prudent however to include these statements with each publication. In my opinion this practice will strengthen the credibility and reliability of the Annals and its high ethical standards. Moreover, the publication of these statements with each manuscript will alert trainees and young practitioners to the importance of ethical principles for medical research involving human subjects stated in the original declaration of Helsinki and its subsequent amendments.2

Thank you.

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References
1. Kamyabi Z, Naderi I, Ramazani A. A randomized, placebo-controlled trial of the effect of pithidine on labor pain, uterine contractions and infant Apgar score. Ann Saudi Med. 2003;23(5):318-320.
2. World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. Available from: URL: http://www.wma.net/e/policy/b3.htm.