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EDITORIAL EXPRESSION OF CONCERN

Editorial Expression of Concern: Effects of calcium–vitamin D co-supplementation on glycaemic control, inflammation and oxidative stress in gestational diabetes: a randomised placebo-controlled trial

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The Editor-in-Chief is issuing an Editorial Expression of Concern for this article. Since publication, several concerns have been raised about the integrity of the article. Specifically:

- According to the Iranian Registry of Clinical Trials (https://en.irct.ir/trial/6041), ethics approval occurred on 20 November 2013, which is after the date the trial is reported to have been conducted (September–November 2013). This suggests retrospective ethics approval.
- This article has similar features to an article published subsequently in *Public Health Nutrition* by some of the same authors [1]. The trials were registered separately (Iranian Registry of Clinical Trials registration nos. IRCT201311205623N11 and IRCT201407115623N23). Both papers report 6 week randomised placebo-controlled trials of calcium and vitamin D in women with gestational diabetes mellitus (GDM). Furthermore, the same general population characteristics, such as mean height, prepregnancy weight and BMI measurements for the placebo group, as well as age, weight change and BMI measurements for the intervention group, are presented in Table 1 in both articles.
- There is concern that the mean baseline serum calcium values given in Table 3 (2.03 mmol/l) are unusually low, and that mathematically incorrect mean values for prepregnancy weight and BMI are given in Table 1 and the results section.
- There is concern that the treatment and placebo tablets were prepared by different companies and would, therefore, have a different appearance to each other.

The detailed concerns have been published as supporting information by Bolland et al [2].

Following receipt of the concerns, the authors noted that the study published in *Diabetologia* was mistakenly reported to have taken place from September 2013 to November 2013 instead of from 21 November 2013 to 30 January 2014. They also stated that the studies presented in this and the later article in *Public Health Nutrition* [1] were separate studies with different sets of participants, although they did confirm that they followed the same set-up in terms of type of supplement and duration of intervention. This was also confirmed by the authors' institutions. The authors stated that some of the data in Table 1 in the *Public Health Nutrition* article were incorrect and that they had notified the journal of this. The authors did not respond to concerns about the mathematically incorrect mean values presented in Table 1, while they noted that serum calcium values lower than 2.03 mmol/l have been reported previously [3].

An investigation into all the concerns was conducted by the National Committee for Ethics in Biomedical Research (NREC), Ministry of Health and Medical Education, Iran. The NREC concluded that there is insufficient evidence that the data were fabricated based on the summary statistics. In line with Iranian legal requirements, the results of this investigation were sent to the research ethics committee at Kashan University of Medical Sciences (KAUMS),

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where the first author is based. The institutional investigation found that the authors had made an error in reporting the timing of the study and that the role of Barij Essence Pharmaceutical Company in providing the placebo tablets and their support for the study should have been made clearer in the paper. However, concerns have been raised regarding a potential conflict of interest with regard to this investigation. Therefore, the Editor-in-Chief advises that readers interpret the paper's findings, including the conclusion regarding the benefits of vitamin D supplementation in pregnant women with GDM, with caution.

All authors agree to the publication of this Editorial Expression of Concern.

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