We fully agree that the best primary outcome is the live birth rate, but we followed the outcome until the delivery of patients. A urine pregnancy test was checked 10 days after the last dose of hCG as the luteal phase support and it is unlikely that the positive pregnancy test is related to the hCG injection.

(4) Clinical pregnancy rate defined as the presence of a fetal sac during an ultrasound examination of 6 weeks after embryo transfer was given in the paper by Paulus et al. (2002). We agree that we should use the clinical pregnancy rate in the sample size calculation. When we designed our study, we were not aware of the study by Paulus et al. (2003), which appeared as an abstract and did not have details about the placebo needle.

(5) We are very cautious about our conclusion that should read as ‘Placebo acupuncture was associated with a significantly higher overall pregnancy rate when compared with real acupuncture’. The overall pregnancy rate that was defined by a positive urinary pregnancy test.

We are aware of the shortcomings of our study design and agree that a three-armed RCT consisting of no treatment, real acupuncture and placebo acupuncture should be performed to address the role of acupuncture in IVF treatment. The contribution of our study (So et al., 2009) is that placebo acupuncture performed in the manner described in our study should not be considered to be inert and those in the placebo group should not be taken as controls.

References

We refer to the letter from Ricci, Bello and Skerk addressed to our recent publication on the use of acupuncture in IVF treatment (So et al., 2009) and would like to answer some concerns about our study.

(1) Four meta-analyses (Cheong et al., 2008; El-Toukhy et al., 2008; Manheimer et al., 2008; Ng et al., 2008) on the role of acupuncture in IVF were published in 2008. Indeed, three meta-analyses (Cheong et al., 2008; Manheimer et al., 2008; Ng et al., 2008) showed that acupuncture improved rates of pregnancy and live birth in women undergoing IVF treatment, contrary to what has been stated in the letter. The meta-analysis by El-Toukhy et al. (2008) is the only one which did not find any improvement in pregnancy and live birth rates following acupuncture. This group published another meta-analysis (El-Toukhy and Khalaf, 2009) in 2009 and the findings were in line with their previous one after adding our study.

(2) In our study, we recruited patients undergoing the first cycle and repeated cycles. We are aware of the impact of the cycle number on the success rate and stratified the randomization sequence according to the cycle number, i.e. the first cycle and repeated cycles. This achieved a nearly identical proportion of the first cycle and repeated cycles in both real and placebo acupuncture groups. We do not feel that the inclusion of those undergoing repeated cycles would affect the conclusion as this is more reflective of the real clinical situation. However, we would agree that further studies should be conducted to find out if acupuncture may work in certain subgroups of patients. The subgroup analysis of the review paper by Manheimer et al. (2008) suggests that the benefit of acupuncture may not be observed in studies with high baseline pregnancy. Therefore, it may be more logical to examine the use of acupuncture in patients undergoing repeated IVF cycles without success.

(3) We fully agree that the best primary outcome is the live birth rate but the live birth rate may not be available because of incomplete data collection. Therefore, we used the most easily available outcome in this study, i.e. the proportion of a positive pregnancy test, but we followed the outcome until the delivery of patients. A urine pregnancy test was checked 10 days after the last dose of hCG as the luteal phase support and it is unlikely that the positive pregnancy test is related to the hCG injection.

Reply: RCT of real versus placebo acupuncture in IVF
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References

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