In Reply:

We thank Dr. Conde-Agudelo for his interest in our article in the March 2019 issue.1 He raised some methodologic issues, which, according to his view, could compromise the study’s internal and external validity. We indeed used block randomization to achieve balance in participants’ allocation. The potential risk for selection bias can be reduced by using random block sizes and keeping the investigators blinded to each block size,2 which was exactly what we did. In fact, our trial is graded as low risk of bias.3 Therefore, any imbalance in patients’ characteristics is solely by chance.

Out of the 1,113 screened women in our trial, 1% had cervical length less than 20 mm and none had cervical length less than 18 mm. This is completely comparable with other studies.4,5 The most likely explanation for the difference with the Nicolaides et al6 trial is that they measured cervical length at 20 0/7–24 6/7 weeks of gestation compared with 16 0/7–22 0/7 weeks in our study and others.1,4

Indeed, twin pregnancies conceived from in vitro fertilization are at slightly higher risk for complications. However, we do not think that the treatment response would be affected by conception method.

We agree that the reduced sample size, updated with a detailed protocol on ClinicalTrials.gov on August 24, 2017, affected our study power. However, this amendment was approved by the ethics committee and documented in the adjusted protocol in the early phase of the study, as well as being clearly addressed in the Discussion section of our article. We did plan an exploratory subgroup analysis in the original protocol, dated on September 25, 2015. The only post hoc analysis performed was the composite of poor perinatal outcomes.

We appreciate all the above-mentioned comments from Dr. Conde-Agudelo. It is of interest to note that the study published by El-Refaei et al,2 with only non–in vitro fertilization twins and incorporated in an individual patient data meta-analysis8 of which Dr. Conde-Agudelo was a co-author, was registered retrospectively.

We believe that our trial has provided new evidence for readers on the prevention of preterm birth in women with twin pregnancies and short cervix.

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REFERENCES

Race, Research, and Women’s Health: Best Practice Guidelines for Investigators

We, black women scholars, clinicians, and public health practitioners, read the article by Ghidei et al published in the April 2019 issue,1 which outlines their considerations for the appropriate use of race in research on women’s health for clinical investigators. We offer four suggestions for the authors and future investigators to consider when deciding whether, when, and how to include race in their research studies. First, we emphasize that black race is not a risk factor; racism is the risk factor for maternal morbidity, mortality, and poor birth outcomes.2 Next, we suggest that investigators engage affected communities in exploring the construction of race and how it shows up in their lives.3 There are methods4 to facilitate this that can deeply influence how research is carried out and its effects on black people’s lives. Third, partnering with critical race scholars, public health practitioners, and transdisciplinary teams is critical.5
Finally, we believe research should champion and reflect a diversified health care workforce. Each point is essential to women’s health research. We look forward to more comprehensive examinations of racism in research and have cited additional sources that include black thought leaders and resources.

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REFERENCES

In Reply: Thank you for your letter. We wrote our article in the hopes of generating more discussion surrounding race, research, and women’s health. We absolutely agree with the important suggestions you make. We hope the readership of Obstetrics & Gynecology continues to contribute to this topic as you have, and we hope that Obstetrics & Gynecology and other journals will convene a group to create formal guidelines regarding the appropriate use of race in research.

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Targeted Treatment of a Rare Vaginal Sarcoma With an Anaplastic Lymphoma Kinase Inhibitor

We wish to update the case report by Forde and Tewari from the February 2016 issue. This was a case of a 34-year-old woman with a history of an epithelioid inflammatory myofibroblastic vaginal sarcoma that recurred 2 months after initial surgical excision. The patient had declined repeat excision and had progression of disease with radiation therapy. Tumor testing identified anaplastic lymphoma kinase gene rearrangements, and the patient was placed on crizotinib 250 mg orally twice daily for 20 weeks. The patient had rapid resolution of her vaginal tumor. A few years after completing treatment, she became pregnant and delivered a healthy neonate. At last follow-up, she remains without evidence of disease for 164 weeks.

This case report is just one of many great examples of how precision medicine has changed management of difficult and rare tumors. Nagumo et al and Butynski et al have reported cases that show drastic improvement in tumor size with use of crizotinib in patients with anaplastic lymphoma kinase rearrangement. Studies such as these have led the National Comprehensive Cancer Network to include crizotinib as standard treatment for patients with inflammatory myofibroblastic sarcomas and anaplastic lymphoma kinase rearrangements.

Given the longevity of our patient and the success of others, we strongly encourage health care providers to perform fluorescence in situ hybridization testing of rare inflammatory myofibroblastic sarcomas to assess for anaplastic lymphoma kinase rearrangements. We hope to encourage other health care providers who treat rare tumor types to continue to advance the field and provide personalized medicine for our patients.

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