OBSTETRICS & GYNECOLOGY

Intrauterine Contraception Among Women Living With Human Immunodeficiency Virus: A Randomized Controlled Trial

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1. What was the primary outcome measure in this study? Discuss whether or not this outcome was the most important in the trial. What alternative primary and secondary outcomes would you have chosen if you were conducting this trial?

2. The authors identified secondary outcome measures including heavy menstrual bleeding and amenorrhea. How were these defined in this trial? What differences existed in these two outcomes between groups? Discuss the strengths and weaknesses of how these outcomes were assessed.

3. What were the discontinuation rates in the two groups? The authors speculate that the discontinuation rates were low due to counseling women received during the study regarding side effects. Draft a counseling script on how you would counsel women considering use of copper or levonorgestrel intrauterine devices. Compare and contrast the risks and benefits of the copper and levonorgestrel intrauterine devices.

4. Discuss clinical scenarios when you might recommend either a copper or levonorgestrel intrauterine device over the alternate device.

5. Discuss the American College of Obstetricans and Gynecologists' (ACOG) Committee Opinion No. 505, "Understanding and Using the U.S. Medical Eligibility Criteria for Contraceptive Use, 2010" (see Obstet Gynecol 2011;118:754–60). Which groups are recommended not to use intrauterine devices?

6. For a patient with human immunodeficiency virus (HIV) who requests contraception, rank the contraceptive methods that you would recommend. Are there any forms of contraception that you would not recommend?

7. Discuss the sample size justification in this study. What difference between groups were the authors looking for? What power did they choose? Define and identify the beta and alpha errors in this trial. What difference in discontinuation rates did the authors actually find between groups?

8. Randomization was generated by alternating blocks. What does this mean? How is this accomplished and why would an investigator choose this method of randomization assignment over simple randomization?

9. How was randomization concealment executed in this trial? What alternative methods might have been employed? What are the risks with this method of concealment?