“Postoperative Levonorgestrel-Releasing Intrauterine System for Pelvic Endometriosis-Related Pain: A Randomized Controlled Trial”

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1. Review the description of the study at ClinicalTrials.gov. What changes have been made in the study design since it was registered in April, 2007? Are these significant changes? Do the changes affect the strength of the study?

2. What is the study design? Is this an effectiveness or and efficacy trial? Justify your answer.

3. The authors claim that this is a “double-blind” study. Do you agree? Were the participants masked to the treatment? Was the assessor nurse masked to the treatment? Discuss possible methods to more effectively mask the participants or the evaluators to the treatment assignment.

4. The control group received no treatment postoperatively. Under what circumstances would you not treat postoperatively someone with endometriosis symptomatic for moderate to severe dysmenorrhea and/or chronic pelvic pain? Discuss whether a different control group would have been more appropriate for clinical care. If so, what treatment should the control group have received?

5. Review the sample size calculation. Did the authors use valid estimates of the primary outcome for the exposures? What conclusions can be drawn from the observations of the secondary outcomes?

6. Read the background information for the 36-Item Short Form Survey (SF-36). Take the test and score yourself. How do the participants’ physical health scores compare with the central tendencies of the Medical Outcomes Study? What does a change in the levonorgestrel group total score of approximately 8 mean? How would your answers need to change in order to yield a similar increase?

7. Review the visual analog scale (VAS) pain scores in Table 2 and Figure 2. Discuss whether any of the differences in median scores between treatment groups are clinically significant. Provide possible explanations for missing data. Do any of those explanations weaken the authors’ conclusions?

8. Review how the authors analyzed participants who were lost to follow-up. Do you agree with the authors’ approach? Discuss possible alternatives.

9. Will this study change your approach to treatment of women with dysmenorrhea? Why or why not?
10. Read Abou-Setta AM, Al-Inany HG, Farquhar CM. Levonorgestrel-releasing intrauterine device (LNG-IUD) for symptomatic endometriosis following surgery. Cochrane Database Syst Rev. 2006 Oct 18;(4):CD005072. In what way(s), if any, should the review be modified?