

## **Uterine Fibroids – Clinical Trial Design & Small Studies: A Clinical Perspective**

Uterine fibroids are benign gynecologic tumors that are treated because of the symptoms they create: abnormal uterine bleeding, pelvic pain, pressure on the surrounding viscera. From a clinician's perspective, medical devices that are used to treat uterine fibroids should be proven safe and effective in reducing these symptoms. As well, patient selection for the use of these devices should take into consideration the patient's age, desire for future fertility and potential short term and long term complications that could add to a reduced quality of life such as pain from adhesions, reduced ovarian reserve and weakening of the uterine wall. Because most patients desiring minimally invasive therapies will not agree to randomized trials, particular attention should be given to control group selection when designing the clinical trials.

### References:

- 1) Wallach E and Vlahos N. Uterine Myomas: An Overview of Development, Clinical Features and Management. *Obstet Gynecol.* 104:393 2004
- 2) Hurst B, Matthews M et al. Laparoscopic myomectomy for symptomatic uterine myomas. *Fertil Steril.* 83:1 2005