DGIM Project Summary

Name of Project: Uterine Leiomyoma Treatment with Radiofrequency Ablation (ULTRA)

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)
Investigator: Dr. Vanessa Jacoby
Research Coordinator and primary contact: Stephanie Lemp
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Research question(s): What are the changes in fibroid-related symptoms from baseline to 3 years after the Radiofrequency Ablation procedure? What are the rate of re-intervention? What is the short-term operative morbidity? What is the “learning curve” for gynecologists performing the procedure? What are the rates of pregnancy and what are the pregnancy outcomes among women who desire future fertility following the Radiofrequency Ablation procedure?

Brief Background/Significance:
Uterine leiomyoma, or fibroids, are benign smooth muscle tumors that occur in 25% of premenopausal women and cause heavy bleeding, pelvic discomfort, urinary and bowel dysfunction, and adverse pregnancy outcomes. Hysterectomy and myomectomy are the mainstay treatments for fibroids. However, many women seek minimally invasive, uterine-preserving therapy to avoid overnight hospitalization and allow for a rapid return to their usual activities. The Radiofrequency Ablation device is a new FDA approved surgical procedure that aims to effectively treat fibroids with a minimally invasive outpatient procedure. Radiofrequency Ablation uses radiofrequency energy to heat fibroid tissue and cause instantaneous cell death. The necrotic cells are then reabsorbed by the lymphatic system resulting in decreased fibroid size and improved symptoms. The Radiofrequency Ablation device is placed within the fibroid under ultrasound guidance during a standard outpatient pelvic laparoscopy.

Inclusion Criteria:
1. Premenopausal (at least 1 menstrual period in last 3 months)
2. Age >21 years
3. Fibroids are associated with heavy bleeding, pelvic pressure or discomfort, urinary or bowel symptoms, or dyspareunia
4. Uterus <16 weeks in size
5. All fibroids <10cm in maximum diameter by ultrasound or MRI assessment within the last year
6. Total number of fibroids <6 by ultrasound or MRI assessment within the last year
7. Had a Pap smear within the last 3 years with appropriate follow-up and treatment for cellular abnormalities
8. Endometrial biopsy indicates no hyperplasia or cancer (biopsy only required if age >45 years and has anovulatory heavy bleeding)
9. Able to tolerate laparoscopic surgery
10. Able to give informed consent
Exclusion criteria:
1. Planned treatment for infertility (male or female)
2. Pedunculated fibroid with thin stalk (total length is <50% maximum diameter of fibroid)
3. All symptomatic fibroids are intracavitary (FIGO Type 0) or submucosal with ≥50% of fibroid within endometrial cavity (FIGO Type 1)
4. Planned concomitant surgical procedure in addition to treatment of uterine fibroids
5. Pregnancy
6. Pelvic infection with the last 3 months
7. History of pelvic malignancy and/or pelvic radiation
8. Known or high suspicion for dense pelvic adhesions

Method of contact/recruitment (be specific): Patients will be recruited at the time of their clinic visit and through advertisements on the web and on flyers posted at UCSF and in the community.

Benefits/burden for participants (clearly identify potential for harm): The risks of participating in the study are mainly risks associated with the procedures. There is also the burden of time for participants because they complete questionnaires. There are potential benefits. Radiofrequency ablation may improve fibroid symptoms and have fewer side effects and faster recovery than myomectomy or hysterectomy.

Any benefits or burden to DGIM practitioners? There is no burden to DGIM practitioners. The benefit to DGIM practitioners is the ability to provide patients with noninvasive treatment options for uterine fibroids.

Timeline for recruitment (projected start and stop dates): July 2013-July 2017

Funding source: Halt Medical, Inc

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular): No.

Do you agree to notify us when recruitment is completed? Yes.

Date form completed: 9/20/13